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P R O C E E D I N G S

(Proceedings commenced at 12:55 p.m.)

(Jury not present.)

THE COURT: Counsel, you wanted to raise a matter?

MR. O'CONNOR: Yeah, Your Honor. This was brought to my attention. So defense used this SEAK expert directory and --

MS. REED ZAIC: Microphone.

MR. O'CONNOR: Pardon me? Oh.

-- the expert directory in cross-examination, and I was told by our team that this was never disclosed. And when our team member approached them, and said that they -- and showed them the order that said that the impeachment exhibits must be delivered to the courtroom deputy 24 hours. I just want to raise that with the Court.

Because I think if it's in the order and we're going to enforce these rules about disclosing exhibits, that's something I think that needs to be enforced here. If there's going to be something not disclosed that's going to be used with a witness for forms of impeachment, I think that the rules have to be complied with.

THE COURT: What is the rule that you think needs to be complied with?

MR. O'CONNOR: The parties met and conferred on the issue exchanging providing to the courtroom clerk with

1 impeachment exhibits 48 hours in advance of trial. The parties  
2 agree they would --

3 THE COURT: Just tell me. Don't read it. Just what  
4 is the --

5 MR. O'CONNOR: It's apparently at Page 69.

6 THE COURT: No. I'm not understanding what the issue  
7 is. Are you saying they didn't put it in an envelope in the  
8 courtroom 24 hours --

9 MR. O'CONNOR: Yeah. There was no -- there was no --  
10 the procedure was not followed. We didn't have appropriate  
11 notice.

12 THE COURT: Well, it would be in an envelope in here  
13 if it's impeachment.

14 MR. O'CONNOR: It was not in an envelope.

15 THE COURT: So the complaint is they didn't put this  
16 in an envelope 24 hours ahead of time?

17 MR. O'CONNOR: Yes.

18 THE COURT: Okay. What are you requesting?

19 MR. O'CONNOR: I just think if it's going to be a  
20 rule, I would like the Court to reinforce that. If we're going  
21 to comply with it, we should comply across the board.

22 THE COURT: Okay. And my understanding is that would  
23 mean it would have been in here yesterday in an envelope.

24 MR. O'CONNOR: Well, yeah. I think there was a  
25 similar one with -- used with Hurst, and I didn't realize that



1 it had not been disclosed.

2 THE COURT: Defense counsel?

3 MR. ROGERS: I'll come up.

4 Your Honor, it was not given to the Court in an  
5 envelope, and the reason why is is that I never had any  
6 intention of submitting it into evidence. And it's not  
7 evidence. It was not tendered. And as the Court has  
8 instructed the jury, that's not evidence because it's not in  
9 the record.

10 And like I said, I never had any intention of ever  
11 entering it. And if I misunderstand the PTO, I will certainly  
12 comply.

13 THE COURT: Well, my view is that it's like a  
14 demonstrative exhibit. You held it up in front of the jury.  
15 You read from it. It should have been marked with an exhibit  
16 number. I didn't say anything because there was no objection  
17 from the plaintiff on that point.

18 But clearly it was used as a demonstrative, at least,  
19 in the courtroom, so it ought to be numbered. It ought to be  
20 in the folder, and we should comply with the rule.

21 MR. ROGERS: I understand, Your Honor.

22 THE COURT: Okay. All right. We'll bring the jury  
23 in.

24 Yeah, you can come back up, Doctor.

25 (Jury present.)

1 THE COURT: Thank you. Please be seated.

2 All right. You may continue, Mr. Rogers.

3 MR. ROGERS: Thank you, Your Honor.

4 DEREK MUEHRCKE, M.D.,

5 called as a witness herein by the plaintiffs, having been

6 previously duly sworn or affirmed, resumed the stand and

7 continued to testify as follows:

8 CROSS-EXAMINATION (Continued)

9 BY MR. ROGERS:

10 Q. Dr. Muehrcke, I hope you had a good lunch.

11 A. Thank you. Good.

12 Q. I believe before we took our break, we were about to talk

13 about a medical record, and that was Exhibit 8731.

14 MR. ROGERS: Can you pull that up, please?

15 And, Your Honor, forgive me. I can't recall if I

16 moved this into evidence before the break. I think I did.

17 THE COURT: You did, and it was admitted.

18 MR. ROGERS: All right. May we display?

19 THE COURT: You may.

20 MR. ROGERS: Scott, if you could, can you go to the

21 final page, please.

22 BY MR. ROGERS:

23 Q. Okay, Doctor. Do you see the signature line there for

24 Richard Shehane?

25 A. Yes.

1 MR. ROGERS: And can you go back to the front page,  
2 please?

3 BY MR. ROGERS:

4 Q. And so, Doctor, I think we were having a little confusion,  
5 because you do see the name Amy Sparks up there, up top;  
6 correct?

7 A. Yes.

8 Q. And, Doctor, would you agree that she's the referring PCP  
9 and that this is Dr. Shehane's record?

10 A. Yes.

11 MR. ROGERS: And if we could, can you go to the review  
12 of symptoms section -- well, the second part down, up there at  
13 the review of systems. Do you see that?

14 And I'll tell you what, why don't you go ahead and  
15 bring up the box above it too. Just do them together. Yeah,  
16 thank you.

17 BY MR. ROGERS:

18 Q. Okay. You got that, Doctor?

19 A. I see it.

20 Q. And, Dr. Muehrcke, would you agree that on this particular  
21 day, Mrs. Hyde, when she presented to Dr. Shehane, the  
22 cardiologist, that she, again, provided information to him that  
23 she was experiencing atypical chest pain?

24 A. Yes.

25 Q. And it does indicate that she had made an -- had contact

1 with Dr. Kuo at Stanford; is that right?

2 A. Correct.

3 Q. But she was not able to get an appointment for a few weeks;  
4 is that right?

5 A. Yes.

6 Q. Okay. And if we could go to the Discussion section on the  
7 next page, please.

8 And, Doctor, do you see the Discussion section there?

9 A. I do.

10 Q. And does it indicate that her echocardiogram showed the  
11 device was in her right ventricle; correct?

12 A. Yes.

13 Q. And then the following sentence reads: There is no  
14 pericardial effusion or evidence of bleeding.

15 Is that correct?

16 A. Yes.

17 Q. And can you tell the jury what pericardial effusion is,  
18 please.

19 A. Fluid in the pericardium.

20 Q. I'm sorry, say again?

21 A. Fluid in the pericardium.

22 Q. And there was no evidence of that; is that right?

23 A. That's what it says.

24 Q. And there was no evidence of bleeding; is that correct?

25 A. Correct.

1 Q. And looking down at the bottom of that record, right above  
2 the doctor's signature, does it indicate that the next visit  
3 was scheduled for August the 12th, 2014?

4 A. Yes.

5 Q. And when we were together before lunch, I think you agreed  
6 with me that Mrs. Hyde had only had two visits with  
7 Dr. Shehane; is that correct?

8 A. Correct.

9 Q. And so are you aware of any visits where Mrs. Hyde returned  
10 to Dr. Shehane after this visit in June of 2014?

11 A. No.

12 Q. And, Doctor, in the records from Dr. Shehane, did you see  
13 any instructions where he had indicated that she should not  
14 elevate her heart rate?

15 A. I did not.

16 Q. And did you see any instructions that she needed to be near  
17 a hospital at all times?

18 A. I did not.

19 MR. ROGERS: All right. You can take that down.

20 BY MR. ROGERS:

21 Q. Doctor, as I believe -- well, I'm sorry. Hang on. I do  
22 need to cover one other opinion.

23 Doctor, I think you testified in the morning that you  
24 believed that there is some possibility that Mrs. Hyde may need  
25 a defibrillator in the future; is that right?

1 A. There's a possibility, yes.

2 Q. And that would be an implantable device that would go in  
3 her heart; is that correct?

4 A. It would be an implantable device that would go in her  
5 shoulder with a wire going into her heart.

6 Q. Right. And those little wires are called leads; is that  
7 correct?

8 A. Those are called leads.

9 Q. And do you have to screw those leads into the heart?

10 A. Typically you screw them in. They can have -- an anchor is  
11 the alternative, but typically you screw them in.

12 Q. And would it be your opinion that the only reason that  
13 Mrs. Hyde may need this implantable defibrillator would be if  
14 she developed arrhythmias later; is that right?

15 A. That's correct.

16 Q. And, Doctor, I think you've also offered an opinion that  
17 Mrs. Hyde is at some risk of sudden death from arrhythmias; is  
18 that correct?

19 A. She's at some risk, yes.

20 Q. And you would agree that that risk wouldn't exist unless  
21 she actually has arrhythmias; right?

22 A. She would have to have an arrhythmia to have sudden death,  
23 yes.

24 Q. And you're not aware of any records that any treating  
25 physicians have diagnosed Mrs. Hyde with any arrhythmias;

1 correct?

2 A. That's correct.

3 Q. And, Doctor, have any of her treating physicians, to your  
4 knowledge, referred Mrs. Hyde to a cardiologist since the strut  
5 and the filter were removed?

6 A. I haven't seen any of the records since then.

7 Q. And are you aware of any reports in the medical literature  
8 of an individual developing a cardiac arrhythmia due to a  
9 filter fragment in the heart?

10 A. Well, I think this is such a new thing -- we're seeing more  
11 and more of these filter fragments -- that I don't think that  
12 anyone's ever studied it.

13 Q. But you're not aware of any reports in the literature?

14 A. That's correct.

15 Q. Doctor, as I understand it from this morning, that you did  
16 not review any of Mrs. Hyde's medical records following the  
17 extraction of the filter and the strut; correct?

18 A. I have not seen -- well, I've seen her deposition saying  
19 that she went into the hospital, I think, February of -- yeah,  
20 February of 2015 with chest pain radiating to her jaw, was  
21 diagnosed with angina. But that's just her deposition report.  
22 I haven't seen any medical records of that.

23 Q. And you wouldn't mind if we took a look at that record,  
24 would you?

25 A. If you look at it?

1 Q. If we took a look at it together.

2 A. I haven't seen it.

3 MR. ROGERS: Well, can you pull up Exhibit 8756,  
4 please.

5 And, Your Honor, I move this into evidence.

6 MR. O'CONNOR: We don't object.

7 THE COURT: Admitted.

8 (Exhibit No. 8756 admitted into evidence.)

9 MR. ROGERS: May I display?

10 THE COURT: You may.

11 BY MR. ROGERS:

12 Q. Doctor, just to get oriented, up in the top right-hand  
13 corner, would you agree that this is a record from February the  
14 4th, 2016?

15 A. Yes.

16 Q. And this is an ER visit; is that right?

17 A. It looks like it.

18 Q. And if we look down to the section on the left-hand corner,  
19 would you agree that the chief complaint that Mrs. Hyde  
20 reported was substernal chest pain radiating to both sides of  
21 the jaw?

22 A. Yep.

23 Q. And, Doctor, were you aware of any tests that were ordered  
24 as part of this ER visit to evaluate her --

25 A. You have me at a disadvantage. I've never seen these



1 records before. This is all new.

2 MR. ROGERS: And if you would, can you pull up  
3 Exhibit 8757, please.

4 And, Your Honor, I move this into evidence.

5 MR. O'CONNOR: No objection.

6 THE COURT: Admitted.

7 (Exhibit No. 8757 admitted into evidence.)

8 MR. ROGERS: May we display?

9 THE COURT: Yes.

10 BY MR. ROGERS:

11 Q. All right. Dr. Muehrcke, do you see where this is the  
12 report of a CT scan that was done on that date?

13 A. Yes.

14 Q. And down at the bottom, under the Impression, do you see  
15 that?

16 A. I see that.

17 Q. And would you agree with me that this is a negative CT of  
18 the chest?

19 A. Yes.

20 Q. And so that's essentially a normal finding; is that right?

21 A. Pardon me?

22 Q. Is that a normal finding?

23 A. A negative finding?

24 Q. Yes.

25 A. It's a negative CT of the chest.

1 Q. Right. And does that mean that there were no abnormal  
2 findings as part of the CT?

3 A. Yeah, no pulmonary emboli.

4 MR. ROGERS: And can you pull up Exhibit 8758.

5 Your Honor, I move this into evidence.

6 MR. O'CONNOR: No objection.

7 THE COURT: Admitted.

8 (Exhibit No. 8758 admitted into evidence.)

9 MR. ROGERS: May we display?

10 THE COURT: You may.

11 BY MR. ROGERS:

12 Q. And, Dr. Muehrcke, is this a report from a nuclear medicine  
13 myocardial perfusion examination?

14 A. That's what it looks like to me.

15 Q. Can you explain to the jury what that is?

16 A. It's a stress test.

17 Q. And if we look down at the bottom, under the Impression  
18 section, do you agree with me it says: No evidence of  
19 stress-induced ischemia.

20 Is that correct?

21 A. I agree with you.

22 Q. And so that's a normal finding?

23 A. I agree with you.

24 MR. ROGERS: And you can take that down, please.

25 And would you pull up 8760.

1 Your Honor, I move this into evidence.

2 MR. O'CONNOR: No objection, Your Honor.

3 THE COURT: Admitted.

4 (Exhibit No. 8760 admitted into evidence.)

5 MR. ROGERS: May we display?

6 THE COURT: Yes.

7 BY MR. ROGERS:

8 Q. Dr. Muehrcke, would you agree that this is the discharge  
9 summary from this ER visit?

10 A. That's what it looks like to me.

11 MR. ROGERS: And if you could, can you go to the --  
12 down to the -- kind of the end of this. And I think it's  
13 probably on the next page.

14 Next page. Next page. I'm sorry. Okay, I'm sorry. Back  
15 up one.

16 Okay. Can you pull out the section that says Hospital  
17 Course.

18 BY MR. ROGERS:

19 Q. And, Dr. Muehrcke, do you see the section that says  
20 Hospital Course?

21 A. I do see that.

22 Q. And you would agree that the discharging doctor noted  
23 Mrs. Hyde's prior history of protein C deficiency; correct?

24 A. Correct.

25 Q. And noted her prior history of pulmonary embolism; is that

1 right?

2 A. Correct.

3 Q. And the doctor noted that she had a CT scan which showed  
4 she had no pulmonary embolism; correct?

5 A. Correct.

6 Q. And as we discussed, the doctor noted that the stress test  
7 was found to be negative; is that right?

8 A. Correct.

9 Q. And does it indicate that the discharge instructions were  
10 to give her Carafate Slurry for atypical presentation of  
11 reflux?

12 A. Yes.

13 Q. And can you tell us what a Carafate Slurry is, please?

14 A. It's for antireflux.

15 Q. And, Doctor, can symptoms of reflux, can those sometimes  
16 provide symptoms that might mimic chest pain or things of that  
17 nature?

18 A. I think so. That's why they gave it to her.

19 Q. And, Doctor, as far as any other care and treatment that  
20 Mrs. Hyde has received since then, would you agree that she's  
21 gotten routine and regular visits with her primary care doctor,  
22 Dr. Lehrner?

23 A. I have not seen her records since she came back from  
24 Stanford.

25 Q. And you wouldn't dispute the notion that she's been to see

1 her primary care doctor routinely?

2 A. I have no opinion.

3 Q. And if one goes for annual visits with a primary care  
4 doctor, does that usually include receiving an EKG at least  
5 once a year?

6 A. I don't know that it does.

7 Q. Okay. And, Doctor, were you aware that Mrs. Hyde is also  
8 seeing her hematologist more than once a year?

9 A. I have not seen the records. I have no opinion.

10 Q. And, Doctor, would you think that Mrs. Hyde's primary care  
11 doctor and her hematologist, when they see her, would inquire  
12 about any sorts of cardiac symptoms that she may have?

13 A. Perhaps.

14 Q. And would you think that those doctors, if they thought it  
15 necessary to refer her to a cardiologist, would do so?

16 A. I would think she should probably see a cardiologist.

17 Q. And if her treating doctors have not referred her to a  
18 cardiologist you would not be critical of them, would you?

19 A. Well, it's a little out of their specialty.

20 Q. And, Doctor, would you think that Dr. Lehrner, her primary  
21 care doctor, and Dr. Thummala, her hematologist, would not have  
22 the medical wherewithal to know if a patient needs to be  
23 referred to a cardiologist?

24 A. I don't know if they feel comfortable doing that.

25 Q. Doctor, let me ask you a few more questions.

1 I believe you told the jury this morning that you  
2 believed that there was some interrelationship between what you  
3 have described as the failure modalities with the Bard filters;  
4 correct?

5 A. Yes.

6 Q. And are you aware of any medical literature that discusses  
7 this interrelation that you described?

8 A. Absolutely.

9 Q. And did you bring that literature with you today?

10 A. No, I didn't bring it with me. It's the EVEREST report,  
11 which Bard funded.

12 Q. And, Doctor, are you aware of any other literature that  
13 describes this as you say?

14 A. Bard documents.

15 Q. I mean medical literature.

16 A. Oh, I'm sorry. No.

17 Q. Okay. And, Doctor, to kind of wrap this up, you reviewed  
18 imaging that showed Mrs. Hyde's filter; correct?

19 A. Yes.

20 Q. And you would agree with me that the imaging demonstrated  
21 that there was a hook on the filter; correct?

22 A. I would have to review them. I can't remember.

23 Q. Okay. Well, if the -- if the image shows that there is a  
24 hook on the top of the filter, would you agree with me that it  
25 is not a Recovery filter?

1 A. Correct.

2 Q. And you would agree with me that it's not a G2 filter?

3 A. Correct.

4 Q. And, Doctor, would you also agree with me that in your  
5 report in this case, you consistently referred to the filter as  
6 a G2 filter?

7 A. I agree.

8 Q. Okay. And was -- strike that.

9 MR. ROGERS: Your Honor, I have no further questions.

10 THE COURT: All right.

11 Redirect?

12 REDIRECT EXAMINATION

13 BY MR. O'CONNOR:

14 Q. Let's talk about your medical/legal work, Dr. Muehrcke,  
15 that you were asked about.

16 Have you reviewed the reports of the experts who have  
17 filed reports on behalf of Bard?

18 A. I have not.

19 Q. I thought you said you looked at other experts' reports.

20 A. I can't -- I can't remember them. I have not reviewed them  
21 for this trial.

22 Q. Have you reviewed them in the past?

23 A. I have to look. I can't remember. I most likely have, but  
24 I cannot remember.

25 Q. Let me just ask you this --

1 A. I apologize.

2 Q. -- do doctors who come in and work with parties in court  
3 cases and explain medical issues to juries, do they charge for  
4 their time?

5 A. I'm sure they do.

6 Q. And the amount that you charge, have you looked to see if  
7 it's in line?

8 A. I think mine's actually a little bit less than a lot of  
9 people's.

10 Q. And why do you do this? Why do you work in the legal  
11 system from time to time?

12 A. Well, I work in the legal system from time to time to take  
13 care of patients, to do what's right, and to make sure that  
14 patients get taken care of. I don't take all cases. I  
15 don't -- I turn down a lot of cases. It's just a lot of time.

16 Q. And you said you turn down cases. And do you work on --  
17 for the side that's been -- is the defendant in lawsuits as  
18 well?

19 A. I've worked on the defendants' side and the plaintiffs'  
20 side, about 50/50 for the medical malpractice.

21 Q. And do you agree there's no issue about doctor care in this  
22 case?

23 A. Yeah. There's no doctors being sued here.

24 Q. Now, you were -- do you recall being asked questions about  
25 that directory, that expert directory?



1 A. The SEAK directory, yes.

2 Q. And you were showed that today?

3 A. Yes.

4 Q. And then the Bard attorney also brought up the fact that  
5 you said a four-letter word.

6 Do you recall that?

7 A. Yes.

8 Q. Have the Bard attorneys ever asked you to look at a  
9 document, of these millions of documents, to look at it to see  
10 if a document would refute the ones you've reviewed?

11 A. No. They've never given me documents to look at.

12 Q. And you know that document we looked at with the G2, the  
13 G2X analysis?

14 A. Yes.

15 Q. You've talked to the Bard attorneys in depositions; right?

16 A. Yes.

17 Q. And then they came here and talked to you today; correct?

18 A. Correct.

19 Q. At any time have they given you anything to show why you  
20 should not rely on their internal documents?

21 A. No, they have not.

22 Q. Have they ever suggested to you, "Doctor, you missed a  
23 couple, and I think if you look at these, you might change your  
24 opinion"?

25 A. No.

1 Q. And, by the way, when you did your report and reported your  
2 opinions, did you reserve the right to amend those opinions?

3 A. Yes, I did.

4 Q. And fair to say that information kept coming to you --

5 A. Yes.

6 Q. -- after your report?

7 Did you receive other information such as depositions?

8 A. Yes.

9 Q. And, Doctor, if you had come across anything that affected  
10 or changed your opinion, would you have notified us and amended  
11 your report?

12 A. Yes.

13 Q. Now, you mentioned that you also looked at a health hazard  
14 evaluation.

15 Do you recall that testimony?

16 A. Yes.

17 MR. O'CONNOR: Can we see Exhibit 2248?

18 I'm sorry. Let me see 443, please. Or 4820, I'm  
19 sorry.

20 BY MR. O'CONNOR:

21 Q. And, Doctor --

22 MR. ROGERS: Your Honor, I'm sorry to interrupt, but  
23 objection. Nondisclosure.

24 MR. O'CONNOR: It's on his list. He was asked  
25 questions about --

1 THE COURT: Well, I haven't heard a question yet.  
2 4820 is in evidence.

3 So let's hear the question, and then if you want to  
4 object, you can, Mr. Rogers.

5 BY MR. O'CONNOR:

6 Q. Well, Dr. Muehrcke, when you were talking about before  
7 that -- and you were explaining the other exhibit about the  
8 rates that were shown in that exhibit, do you recall that  
9 testimony?

10 A. Yes, the fracture analysis.

11 Q. I thought I heard you mention that that came on the tail of  
12 a health hazard evaluation.

13 A. Yes.

14 Q. And is Exhibit 4820 the health hazard evaluation you were  
15 referring to?

16 A. Yes, it is.

17 Q. And is this something that you reviewed and relied upon in  
18 your opinions?

19 A. Yes, it is. It talks about the --

20 MR. O'CONNOR: Hang on.

21 May I publish this to the jury, Your Honor?

22 THE COURTROOM DEPUTY: I don't show 4820. I show  
23 4800.

24 THE COURT: Hold on just a minute. I show it in  
25 evidence.

1 THE COURTROOM DEPUTY: Yes. I'm sorry. The 19th,  
2 yes.

3 THE COURT: Yes, you may.

4 BY MR. O'CONNOR:

5 Q. And, Dr. Muehrcke, can you --

6 MR. ROGERS: Your Honor, objection. Nondisclosure.

7 THE COURT: Are you going to have him opine about the  
8 document?

9 MR. O'CONNOR: I was just going to have him put his  
10 answer in context as to why this was important to the questions  
11 on the other document about rates he reviewed.

12 THE COURT: Is that in his report?

13 MR. O'CONNOR: Pardon me?

14 THE COURT: Is that in his report?

15 MR. O'CONNOR: No. I'm just doing a redirect because  
16 he was asked about that.

17 THE COURT: Objection sustained.

18 MR. O'CONNOR: Okay. I'll move on.

19 BY MR. O'CONNOR:

20 Q. Doctor, on cross-examination you were asked about all  
21 filters and whether all filters fail, fracture, migrate.

22 Do you recall those questions?

23 A. Filters can have the problems, yes.

24 Q. In your experience, though, is Bard different?

25 A. Bard is different.

1 Q. Why?

2 A. The Bard filters are different because not only do they  
3 have the problems of caudal migration, tilt, perforation, and  
4 fracture, but they all occur together in a much higher rate.

5 Q. And you mentioned the EVEREST report in response to  
6 questions by defense counsel?

7 A. Yes.

8 Q. And what report is that? Did that involve Bard filters?

9 A. The EVEREST report is a -- it's one of two prospective  
10 trials which Bard funded which were short-term trials to look  
11 at the retrievability, not the long-term safety, of filters.  
12 The first study, the Asch study, was for the Recovery filter,  
13 and this one was for the G2 filter.

14 Q. And what was your point about that study?

15 A. Well, there's a -- they -- I've had a chance to see the raw  
16 data, and the authors came to the conclusion that there was a  
17 statistically significant association between caudal migration  
18 and tilt. And the data in the -- the raw data of the filters  
19 shows that only 35 percent of filters which are placed in  
20 position --

21 MR. ROGERS: Your Honor, objection. I think we're  
22 getting into an area beyond the Daubert order.

23 THE COURT: Overruled. I think this is within the  
24 scope of cross.

25

1 BY MR. O'CONNOR:

2 Q. Can you finish your answer, please?

3 A. Just that the raw data from the EVEREST study showed that  
4 only 35 percent of the G2 filters which were placed stayed  
5 where they were placed. They moved either up or down, mostly  
6 caudally.

7 Q. And when Bard's counsel asked you questions about Bard  
8 documents and asked you to look at those rates, do you recall  
9 those questions?

10 A. Yes, sir.

11 Q. And he showed the figures of filter -- Bard filters that  
12 were distributed or sold?

13 A. Yes.

14 Q. Is that helpful in trying to figure out what's really  
15 happening out there?

16 A. It's the only data which was available to be assessed. But  
17 that data is MAUDE data, and it's data which is voluntarily  
18 submitted by doctors or by the manufacturer, and it  
19 tremendously underestimates the amount of complaints.

20 Q. Now, you were asked about patients who have failed filters  
21 but may be asymptomatic. Is that something that medical device  
22 companies should not be concerned about?

23 A. They should be very concerned about that. You know, you  
24 can be asymptomatic from a lung cancer, but you'd still take it  
25 out. You don't know -- these things progress.

1 Q. And in terms of the medical records you were asked about in  
2 2016 regarding Lisa Hyde --

3 A. Yes.

4 Q. -- by that time, she had her filter out?

5 A. Yes.

6 Q. And did those records show she hadn't had a PE without a  
7 filter?

8 A. They showed she did not have a PE without a filter present,  
9 yes.

10 Q. And when -- simply because a patient has a filter and  
11 doesn't have a PE during that period, does that mean somehow  
12 the filter -- can you say under those circumstances  
13 automatically the filter stopped a clot?

14 A. No, you can't. In her situation, she had three DVTs. Two  
15 of them were associated with pulmonary emboli. Each time they  
16 affected her right leg. The first two affected her calf; the  
17 third DVT affected her thigh.

18 So she had no episodes of leg swelling, which is where  
19 99 percent or 95 percent of pulmonary emboli originate from.  
20 So I don't think she had a DVT or a PE in the past.

21 Q. When Mr. Rogers was asking you about those internal  
22 documents that purported to show rates, do you recall that?

23 A. Yes.

24 Q. How do you -- what do you think -- how do you respond to  
25 what you saw?

1 A. Well, I think there should be no rate. I think the rate  
2 should be zero for any adverse events, as close to zero as  
3 possible.

4 Q. And when you reviewed -- did your work in this case, and  
5 you saw documents that nobody else has seen other than the  
6 experts in this case, other than Bard, what do you think Bard  
7 should have done during the time of those documents?

8 A. Well, I think that, you know, no one knows more about their  
9 device than the medical device company. And my feelings are  
10 just like the medical doctor who did the EVEREST study; I think  
11 the G2 filter should have been pulled from the market.

12 Q. And should doctors be able to rely on medical device  
13 companies to be honest and forthright?

14 A. Yes.

15 Q. Is that why you've told this jury that Bard should have  
16 disclosed that information?

17 A. I think it would be -- yes. That would be very helpful to  
18 get that information.

19 Q. Did Bard ever disclose that to you when you were out there  
20 helping your patients?

21 A. No.

22 MR. O'CONNOR: That's all I have.

23 THE COURT: All right. You can step down, Doctor.

24 (Witness excused.)

25 MR. LOPEZ: Your Honor, at this time, the plaintiffs



1 call Mr. Alex Tessmer.

2 THE COURTROOM DEPUTY: Sir, if you'll please come  
3 forward. You can stand right here and raise your right hand,  
4 please.

5 THE WITNESS: Sure.

6 (The witness was sworn.)

7 THE COURTROOM DEPUTY: Please state your name and  
8 spell it for the record.

9 THE WITNESS: Alex Tessmer. A-L-E-X, T-E-S-S-M-E-R.

10 THE COURTROOM DEPUTY: Thank you very much.

11 MR. LOPEZ: Excuse me one second.

12 Your Honor, I have a copy of Mr. Tessmer's deposition  
13 that was taken. He might need to reference it. Can I give it  
14 to the clerk to give to the witness?

15 THE COURT: You can, yes.

16 MR. LOPEZ: Thank you.

17 May I proceed? May I proceed, Your Honor?

18 THE COURT: You may.

19 ALEX TESSMER,  
20 called as a witness herein by the plaintiffs, having been first  
21 duly sworn or affirmed, was examined and testified as follows:

22 DIRECT EXAMINATION

23 BY MR. LOPEZ:

24 Q. Good afternoon, Mr. Tessmer. How are you?

25 A. Good afternoon. Doing well. How are you?

1 Q. Good.

2 I know that this is -- you've been here a couple days, and  
3 I apologize for some of the delays. We intended to get you on  
4 sooner, so I'll keep that in mind as we proceed. Okay?

5 A. Thank you.

6 Q. Introduce yourself to the jury, please.

7 A. Sure. My name is Alex Tessmer. I am an ideation marketing  
8 manager at Bard.

9 Q. And before you were a marketing manager at Bard, did you  
10 work in some capacity with Bard's IVC filters?

11 A. Yes, I did.

12 Q. And do you have an engineering degree?

13 A. No, I do not.

14 Q. I think you -- were you trained in -- I think you have a  
15 degree in chemistry; correct?

16 A. That's correct. I have a Bachelor of Science in chemistry  
17 with a biochemistry emphasis.

18 Q. And did you have an engineering position at some point when  
19 you were working at Bard?

20 A. Yes, I did.

21 Q. And I believe you actually started at Bard in 1998; does  
22 that sound about right?

23 A. January 1997.

24 Q. Okay. And you left in 2005?

25 A. That is correct.

1 Q. And then you returned sometime after that; is that right?

2 A. Correct.

3 Q. And were you involved with filters between 2002 and 2005?

4 A. Yes.

5 Q. And that would have been primarily the Recovery filter era,  
6 or phase, of Bard filters?

7 A. That's correct.

8 Q. Now, I think in 2005 they were at least trying to get the  
9 G2 on the market. Did you do any work on the G2?

10 A. Not that I recall. My primary purpose was working on the  
11 jugular delivery system. So I know at some point I probably  
12 saw the design and tried to make it work with that --

13 Q. Okay.

14 A. -- the delivery system.

15 Q. And what is ideation marketing manager?

16 A. So basically what my role is now is I work a lot with  
17 doctors. I go to different conferences. And we're really  
18 trying to determine the unmet needs within a market and  
19 develop -- come up with the next best ideas, if you will, and  
20 look at the business case and also look at the clinical and  
21 economic value proposition to see if there's something we can  
22 develop to help doctors help patients.

23 Q. And today you have no involvement with IVC filters;  
24 correct?

25 A. That is correct.

1 Q. In fact, since you rejoined Bard in 2012, you've been in  
2 the marketing department?

3 A. That is correct, and now I'm technically in R&D, but...

4 Q. So we want to talk about that time period when you were at  
5 Bard and working on filters.

6 A. Okay.

7 Q. And were you -- was your -- did you have like a position or  
8 a title? Were you considered -- were you called an engineer or  
9 did you have some kind of -- where they designated you in some  
10 position?

11 A. Yeah. I was a -- I believe it was an Engineer II at that  
12 time.

13 Q. Okay. What does that mean?

14 A. That means there's an Engineer I, Engineer II, so basically  
15 I was an engineer working on a project, which was the jugular  
16 delivery system, used for a jugular approach to deliver the  
17 filter.

18 Q. So your focus during those three years was with engineering  
19 concepts and working with fellow engineers at Bard?

20 A. I was working with fellow engineers, correct.

21 Q. And did you -- who did you report to during that period of  
22 time?

23 A. Most of the time I reported to Rob Carr.

24 Q. And when did you first get involved in doing any kind of  
25 work on the Recovery filter?

1 A. So the work I got involved with, I believe it was in  
2 October 2002. And I basically joined the team to work on a  
3 jugular delivery system.

4 Q. Okay. Did there come a time when instead of you doing that  
5 sort of work, in other words, prospective work on maybe  
6 something new, that you got drawn into evaluating the  
7 performance of the Recovery filter?

8 A. I did get called in to help, to help on some testing with  
9 the filter.

10 Q. Was there a team known as the Filter Franchise Team?

11 A. Yes, there was.

12 Q. And were you on that team?

13 A. Yes, I was.

14 Q. And we're going to come back, but I'm going to try to put  
15 some perspective here.

16 So you're familiar that there was a G2 filter after  
17 the Recovery filter; correct?

18 A. That's what I understand, correct.

19 Q. Is it also your understanding that the reason there became  
20 a G2 filter because there was some design issues with the  
21 Recovery filter?

22 A. What I understood is we're continually ideating at Bard.  
23 We always try to create new devices. So my understanding for  
24 that device is we were coming out with another device to  
25 market.

1 Q. And I understand that's what you wanted to say, but please  
2 listen to my question.

3 A. Sure.

4 Q. My question was whether or not the G2 filter evolved  
5 because of some design issues and problems that the company had  
6 with the Recovery filter. Can you answer that yes or no?

7 A. I can answer that I understood that there were some -- I  
8 think, if I recall, there were some different complaints and  
9 they were looking into some things.

10 Q. Well, there were some complaints that potentially were  
11 related to the manner in which the Recovery filter was  
12 designed; correct?

13 A. I don't know if I could say that for certain.

14 Q. Pardon me?

15 A. I don't know if I could say that for certain.

16 Q. Well, let me ask you this question.

17 A. Sure.

18 Q. You changed the G2 to a design that was different than  
19 Recovery filter; true?

20 A. Yes. We --

21 Q. And those design changes were made specifically to try to  
22 improve what had previously been not a very good performance by  
23 the Recovery filter once implanted in human beings; true?

24 A. What I'd say, we were always trying to --

25 Q. Is that true, what I just said?

1 THE COURT: Hold on just a minute.

2 If he asks you for a yes or no answer, give it if you  
3 can. But if you can't, tell him you can't answer it yes or no.

4 THE WITNESS: Okay.

5 BY MR. LOPEZ:

6 Q. Is that true that the G2 filter design changes were made  
7 because of experiences that were happening with the Recovery  
8 filter where real human beings were having some problems with  
9 the Recovery filter and having complications and injuries?

10 A. I would defer to Rob Carr to answer that.

11 MR. LOPEZ: Well, let's -- can we have 2059 exhibit,  
12 please, Felice.

13 BY MR. LOPEZ:

14 Q. You were a member of the franchise -- Filter Franchise  
15 Team; correct?

16 A. Yes, that's correct.

17 Q. And was Rob Carr the team leader?

18 A. Yes, he was.

19 Q. And do you remember what department you represented on that  
20 team?

21 A. Engineering.

22 Q. Okay. Do you see this document I'm looking at right now?  
23 Are you familiar with that document?

24 A. Yes. I've seen it before.

25 MR. LOPEZ: Your Honor, I would like to offer 2059

1 into evidence and publish it to the jury.

2 MR. CONDO: No objection.

3 THE COURT: Admitted.

4 (Exhibit No. 2059 admitted into evidence.)

5 MR. LOPEZ: So, Felice, I just need -- first of all,  
6 can we --

7 BY MR. LOPEZ:

8 Q. This document is dated October 27, 2003. See right there  
9 at the bottom?

10 A. Yes, I see that.

11 Q. And this was -- the Recovery filter had already gotten  
12 cleared as a retrievable filter by then; true?

13 A. I believe so.

14 Q. All right.

15 A. I don't quite recall.

16 Q. And -- but as of that date, the Recovery filter had not  
17 gone through what the company would call full market launch.  
18 Do you remember that?

19 A. Yeah. I don't -- yeah, I don't know -- I don't recall one  
20 way or another on the full market release.

21 MR. LOPEZ: Felice, could you enlarge the top  
22 one-third of this exhibit? Perfect.

23 THE WITNESS: Thank you.

24 BY MR. LOPEZ:

25 Q. Do you see that well enough?



1 A. Yeah. That helps. Yep.

2 Q. So you see there where it says: Launch date, January 26th,  
3 2004?

4 A. Yeah. I see that's the latest best estimate that they were  
5 anticipating a launch, it looks like, in January 2004.

6 Q. And that was in the U.S.; right?

7 A. I believe so.

8 Q. Well --

9 A. It says U.S., yes, correct.

10 Q. And then there was -- the plan was then to launch in Europe  
11 in the second quarter of 2004?

12 A. That's what it appeared -- that's what it says in this  
13 document, correct.

14 Q. And there are you, Alex Tessmer, right there; right? R&D?

15 A. That is correct.

16 Q. What is R&D?

17 A. Research and development.

18 Q. And there's Mr. Carr?

19 A. Correct.

20 Q. All right.

21 MR. LOPEZ: So could we have 1006, please, Felice?

22 And could you show Mr. Tessmer page 2? One before  
23 that. There you go.

24 BY MR. LOPEZ:

25 Q. Are you familiar with that memorandum, Mr. Tessmer?

1 A. Yes, I am.

2 MR. LOPEZ: Okay. Your Honor, I'd like to offer  
3 Exhibit 1006.

4 MR. CONDO: No objection.

5 THE COURT: Admitted.

6 (Exhibit No. 1006 admitted into evidence.)

7 MR. LOPEZ: May I publish it to the jury, Your Honor?

8 THE COURT: Yes.

9 MR. LOPEZ: Thank you.

10 Can we just go to the first page, Felice, quickly?  
11 And I don't mean to rush you. I'm meaning I don't need it for  
12 very long.

13 BY MR. LOPEZ:

14 Q. You're on this email; right?

15 A. Yes.

16 Q. This document was sent to you? Do you see your name there  
17 in the "To"?

18 A. That is correct.

19 Q. All right. And who's Mr. Hudson?

20 A. Brian Hudson worked in quality.

21 Q. And who's Mr. DeCant?

22 A. I believe at the time he was the vice president of R&D.

23 Q. And who's Mr. Uelmen?

24 A. I think he was a vice president of quality.

25 Q. And Janet Hudnall, do you remember that she was the

1 marketing director for the filter?

2 A. Yes.

3 MR. LOPEZ: All right. So if we go to the next page,  
4 please. And just -- we're going to walk through this, Felice.  
5 Why don't we do a third of the page at a time so the witness  
6 and the jury can both see this.

7 BY MR. LOPEZ:

8 Q. So this was a special design review for the Recovery  
9 filter.

10 Do you see that?

11 A. Yes, I do.

12 Q. And do you remember the purpose -- without looking at the  
13 document, just from memory -- why there was a meeting about a  
14 month before the product was going into full market launch in  
15 the United States and about four months before full market  
16 launch in Europe that all of you were getting together to have  
17 a design review meeting?

18 A. Yeah. So, again, I was called -- what I recall, I was  
19 called in to do some testing. And some of the information on  
20 here talks about the testing that they wanted me to perform.

21 Q. Okay. Testing that had not been performed before the  
22 Recovery filter was submitted for clearance by the FDA?

23 A. I believe there -- for some of the testing I was doing, I'm  
24 not sure what or what had not been performed before or after.

25 Q. But testing that was done before that had not done -- that

1 had not been done before the company had decided it was going  
2 to launch it nationwide in the United States and throughout  
3 Europe; correct?

4 A. They were doing --

5 Q. Is that true?

6 A. Repeat the question, please.

7 Q. I'll just go on to the next question.

8 A. Okay.

9 Q. Let's just look at the document. If you look at --

10 A. Sure.

11 Q. -- the purpose of this special review meeting, it's in the  
12 very first paragraph.

13 MR. LOPEZ: Can you highlight that, where it says "The  
14 purpose" and down, just down to January 2004.

15 BY MR. LOPEZ:

16 Q. You can see that okay, can't you?

17 A. Yes, I can. Thank you.

18 Q. All right. So: The purpose of this special review was to  
19 gain further understanding related to the design elements of  
20 these products in anticipation of the up-and-coming full market  
21 release in January of 2004.

22 Do you recall that being the purpose of the meeting?

23 A. Yes. That's what it says in the document.

24 MR. LOPEZ: And let's go down to, Felice, where --  
25 right on "The elements." There you go.

1 BY MR. LOPEZ:

2 Q. And: The elements that were reviewed during the meeting  
3 are outlined in an earlier memorandum.

4 So you actually got an earlier memorandum about this  
5 meeting; correct?

6 A. I might have. I'd have to take a -- I'd have to see it. I  
7 don't recall. That was, again, over 13 years ago.

8 Q. And that meeting that we're talking about in this memo was  
9 based on a review upon the degree of risk obtained from a  
10 design failure modes and effect analysis, a DFMEA.

11 Do you see that?

12 A. I see that.

13 Q. For the Recovery filter?

14 A. Yes, I see that.

15 Q. And a DFMEA, could you -- we've had some testimony about  
16 that already in this trial. Could you tell the jury what a  
17 DFMEA is?

18 A. Yeah. So it's a design failure modes and effect analysis.  
19 Basically, we're trying to assess the risk and the harm that a  
20 medical device could have on a patient.

21 Q. And was there some DFMEA that was run about that that  
22 suggested that maybe that was something that was already  
23 happening with the Recovery filter after it had been cleared  
24 and already being sold?

25 A. I would have to defer to Brian Hudson, because he was in

1 charge of the DFMEA. There definitely was a DFMEA. I just  
2 don't recall the exact.

3 MR. LOPEZ: Okay. Let's go to number 3 at the bottom  
4 of this exhibit.

5 BY MR. LOPEZ:

6 Q. And, sir, that relates to the issue of migration.

7 Do you see that?

8 A. Yes, I do.

9 Q. Now, were you aware that there had already been some issues  
10 with migration with the Recovery filter prior to this meeting  
11 and prior to full market release?

12 A. So in my testimony review, yes.

13 Q. Okay. And as part of your preparation for this meeting,  
14 and maybe you've refreshed your recollection as well about  
15 this, there had been a migration in a very small study done in  
16 Canada by a Dr. Asch on the Recovery filter.

17 Were you aware of that?

18 A. I think I recall something about that from prior testimony,  
19 but I do not know the exact specifics.

20 Q. And after Dr. Asch's study and Bard got a clearance to sell  
21 and market the Recovery filter, there were similar results that  
22 Dr. Asch experienced in this small study that he had done for  
23 retrievability. True?

24 A. I don't know.

25 Q. You just don't remember or --

1 A. I don't recall.

2 Q. Okay. So this meeting was -- one of the things this  
3 meeting was going to be related to was reviewing to see  
4 objective evidence of the following elements:

5 a. Documentation that explains the establishment of  
6 the 50 millimeter of mercury acceptance criteria for migration  
7 resistance.

8 Do you see that, sir?

9 A. Yes, I do.

10 Q. And what does that mean?

11 A. It's asking for documentation explaining establishment of  
12 50 millimeters of mercury.

13 Q. Wasn't there some concern at that time that Bard had  
14 established that to be their safety threshold and that they  
15 ought to -- they might ought to think about using a different  
16 threshold of safety for migration resistance?

17 Can you answer that yes or no?

18 A. I do not know. I'd have to defer to Rob for that.

19 Q. Okay. Now, let's go to page 2, please.

20 And then at this same meeting, there is discussion  
21 about some of the additional studies that should be done on the  
22 Recovery filter; true?

23 A. True. That's what it says on the document, correct.

24 Q. And b describes one of those: A migration resistance study  
25 that analyzes the performance of the Recovery filter in

1 conjunction with tilting and the quality of the legs and the  
2 hooks.

3 Do you see that?

4 A. Yes, I do.

5 Q. And then the next one is: A migration resistance study  
6 that compares the Recovery filter to competitive products, for  
7 example, the Greenfield.

8 True?

9 A. Yes.

10 Q. Now, as far as you know, neither one of those two tests had  
11 ever been run before on a Recovery filter; right?

12 A. I don't recall. I'd have to defer to Rob because I was the  
13 guy just brought in for testing.

14 Q. They didn't show you a test that was similar to that  
15 that -- so you could look at it to see if you should design  
16 your test the same or differently?

17 A. I did have a copy of the design verification and  
18 validation, I believe, if I can recall, from NMT which we tried  
19 to duplicate the testing, correct.

20 Q. Well, let me ask you this question.

21 A. Sure.

22 Q. Are you -- other than the tests that we're going to be  
23 talking about here in a minute and that are described here,  
24 before Recovery was launched, were there any migration  
25 resistance tests that compared the Recovery filter to



1 competitive products that you're aware of?

2 A. I'm not aware of.

3 Q. Were there any radial force studies that compared the  
4 Recovery filter to competitive products there at number d, or  
5 letter d?

6 A. I do not know.

7 Q. Okay. So let's look at 2062, please. Exhibit 2062.

8 So that was in December of 2003. And then in -- you  
9 see the next document there, the memorandum from Rob Carr?

10 A. I see it.

11 Q. And you would have gotten a copy of this memorandum because  
12 it -- wouldn't you agree that this is a memorandum in response  
13 to those issues that were raised in the December minute meeting  
14 that we just discussed?

15 A. Not -- I mean, I can't recall exactly. My name's not on  
16 the document. Is there another page with my name on it, maybe?

17 Q. You were still on the team; right?

18 A. Yes, I was.

19 Q. This talks about tests that you ran, ultimately. Wouldn't  
20 you agree that you probably would have gotten a copy of this  
21 memo?

22 A. I possibly might have gotten a copy. That's fair.

23 MR. LOPEZ: Your Honor, I'd like to move to admit 2062  
24 at this time.

25 MR. CONDO: No objection.

1 THE COURT: Admitted.

2 (Exhibit No. 2062 admitted into evidence.)

3 MR. LOPEZ: May I publish it to the jury?

4 THE COURT: Yes.

5 BY MR. LOPEZ:

6 Q. I'm not going to go through every single item in here, I  
7 promise. So let's look at the full page for a moment.

8 This has those issues that were raised -- that were on  
9 that document that we just looked at before, and then there's  
10 some answers here, responses to each of those. Do you agree  
11 with that?

12 A. It appears that way.

13 Q. And there's some dates here about when some of these things  
14 are going to take place; correct?

15 A. There are some dates on there, correct.

16 Q. For example, if you look down there at the bottom, where it  
17 says: The DFMEA was updated and approved on QUMAS.

18 Do you see where I am?

19 A. Oh, yes, I do. Thank you.

20 Q. And the DFMEA, was that -- what you just described. They  
21 updated that; right?

22 A. According to this document, yes.

23 Q. And there was nothing about that DFMEA that was updated  
24 that caused you and the company to not go forward with all  
25 these tests; true?

1 A. Not that I'm aware of.

2 Q. So let's look at, for example, b at the very bottom, 3b,  
3 where there was going to be a migration resistance study that  
4 analyzes the performance of the Recovery filter in conjunction  
5 with tilting and the quality of the legs and hooks.

6 Do you see where I am right there at the bottom?

7 A. Yes, I see that.

8 Q. And that test was going to be conducted on March 12, 2004;  
9 right?

10 A. I don't -- I'm not seeing the date on here.

11 Q. The next page, I'm sorry. My bad. My apologies.

12 A. No problem.

13 Q. Right at the very top. There.

14 And then if you go down to the next test that's going  
15 to be run, it's migration resistance study that compares the  
16 Recovery filter to competitive products.

17 Do you see that?

18 A. Yes, I do.

19 Q. And that was going to be conducted on March 12, 2004?

20 A. That's what it says in the document, yes.

21 Q. And if you look at just the page -- if we can look at the  
22 full page again -- all of these tests that were going to  
23 analyze the migration resistance of the Recovery filter were  
24 all scheduled to take place after the company was going to  
25 launch the Recovery filter into the open U.S. market; true?

1 A. It appears that way, yes.

2 Q. And there was nothing about the fact that you had no idea  
3 about the results of this test that stopped the company from  
4 launching the Recovery filter widely in the United States;  
5 true?

6 A. There was nothing -- so, again, I was the guy pulled into  
7 testing. I'd defer Rob Carr to that, to answer that.

8 Q. My point is: You didn't have the results of these tests  
9 that had never been run before on the Recovery filter, and you  
10 still launched the Recovery filter widely across the United  
11 States in January of 2004. True?

12 A. Well, there was migration testing done, but specifically  
13 these tests, perhaps not. I'm not completely sure on that.

14 Q. Okay. Let's go to one of the tests.

15 MR. LOPEZ: Can we have 1383, please?

16 BY MR. LOPEZ:

17 Q. Now, this is -- is this one of the tests that were earlier  
18 described that you actually ran?

19 A. So I was the one that wrote the protocol and report, and I  
20 had technicians run the test.

21 Q. You oversaw the test, made sure they followed the protocol  
22 of the test, and made sure the test was run properly; correct?

23 A. That is correct.

24 MR. LOPEZ: And I'd like to offer at this time 1383,  
25 Your Honor.

1 MR. CONDO: No objection.

2 MR. LOPEZ: May I publish to the jury?

3 THE COURT: Admitted.

4 (Exhibit No. 1383 admitted into evidence.)

5 THE COURT: You may publish.

6 MR. LOPEZ: I'm sorry.

7 May I publish, Your Honor?

8 THE COURT: You may.

9 BY MR. LOPEZ:

10 Q. Okay. This is a characterization of Recovery filter  
11 migration resistance in comparison to competitive product.

12 Do you see that?

13 A. Yes.

14 Q. If we go to the next, very next page -- and you wrote this  
15 protocol?

16 A. This is the engineering report.

17 Q. Okay. But --

18 A. And I wrote the protocol, too, yeah.

19 Q. Okay. Thank you.

20 So the objective --

21 MR. LOPEZ: Can we just look at the very -- 1.0  
22 there, Felice, under Objective.

23 BY MR. LOPEZ:

24 Q. So the objective of this study was to compare the Recovery  
25 filter to competitive products in relationship to migration

1 resistance.

2 Do you see that, sir?

3 A. Yes, I do. Correct.

4 MR. LOPEZ: And if we go to the 2.0, the last  
5 paragraph, and this -- I'm sorry. 2.0, not the last paragraph.  
6 The second to the last paragraph. "In conjunction with the  
7 field activities."

8 If you can just blow that part up. Thank you.

9 BY MR. LOPEZ:

10 Q. So this refers back to the design review meeting we talked  
11 about earlier in December of 2003; right?

12 A. That is correct.

13 Q. And that -- this also confirms that that meeting was to  
14 gain a further understanding of the design elements of this  
15 product; true?

16 A. That's what it says, correct.

17 Q. And in preparation of this design review, the DFMEA for  
18 Recovery filter was analyzed for critical elements to be  
19 discussed during the review; true?

20 A. That is what it says, correct.

21 Q. And migration resistance was one of the critical elements  
22 identified for review; true?

23 A. True.

24 Q. And now, sir, as of this date, as of the date you had that  
25 review, there was already a migration of a Recovery filter in a

1 patient that caused a catastrophic injury. Do you recall that?

2 A. I do not recall the specifics, but I know there was -- I  
3 think I recall that there was some type of migration.

4 Q. And there were some serious migration issues with the  
5 Recovery filter that caused your team to get together before  
6 market launch and make a decision that maybe we ought to test  
7 this device differently than we may have tested it before we  
8 got clearance at FDA; true?

9 A. I would have to defer to Rob on that.

10 Q. And there had already been, before full market release,  
11 when this team got together and now you're trying to -- what  
12 did you say -- get a further understanding of the design  
13 elements of the product, a fracture like Dr. Asch had  
14 experienced in his small study. But instead, that fracture  
15 actually embolized through the vena cava and went into a  
16 patient's heart.

17 You knew about that, right, before these tests?

18 A. I'm not sure if I was made aware of it during these tests  
19 or after it, but yes.

20 Q. You know two lesser events happened in the Asch study.  
21 You're aware of that?

22 A. I don't know the exact details with Dr. Asch 's study.

23 Q. Okay. Dr. Asch had a fracture that was able to be removed  
24 without causing any injury to the patient. You know about  
25 that; right?

1 A. Again, I -- I don't know anything about -- I haven't read  
2 any of Dr. Asch's studies or dove into that. I was on the team  
3 to work on the jugular delivery system and pulled in, so -- and  
4 I don't recall exact specifics.

5 Q. Let me share with you --

6 A. Sure.

7 Q. -- some evidence that's come into this case.

8 In the Asch pilot study in Canada, where patients were  
9 being very closely monitored --

10 A. Okay.

11 Q. -- there was a migration that -- after it got hit by a clot  
12 that went 4 centimeters towards the patient's heart.

13 A. Okay.

14 Q. And as a result of that, those involved in the study,  
15 including the ethics board, stopped the study.

16 Were you aware of that?

17 MR. CONDO: Your Honor, I think witness -- counsel is  
18 testifying.

19 THE COURT: Sustained. I think he said he doesn't  
20 know the details of the Asch study.

21 BY MR. LOPEZ:

22 Q. Well, let's put it this way: After the results of the  
23 early marketing of the Recovery filter prior to full market  
24 release, whatever incidents that happened in the open market  
25 where people weren't being monitored in a clinical trial, Bard



1 did not stop selling the Recovery filter; true?

2 A. The Recovery filter was still being sold, correct.

3 MR. LOPEZ: So the objective -- where are we on this?

4 Okay. Let's go down to Test Procedure, please. 4.0.

5 And I'm just doing this so the jury can see these  
6 names.

7 BY MR. LOPEZ:

8 Q. And this test was designed to compare the migration  
9 resistance of the Recovery filter against -- I mean, is that  
10 virtually every device that was on the market, both retrievable  
11 and permanent?

12 A. I believe it was most of them in the U.S., anyway.

13 Q. So you didn't take the Recovery filter and separate it out  
14 and say "We just have to be as migration resistant as other  
15 permanent devices that have retrievables" and test it that way  
16 and not test it just against permanent devices; true?

17 You tested it against devices that had permanent  
18 indications and some that had both retrievable and permanent  
19 indications; correct?

20 A. Yes. I believe they all had -- yeah. They had some  
21 retrievable ones in there, correct.

22 Q. And you're somewhat familiar with the 510(k) process,  
23 aren't you?

24 A. Somewhat.

25 Q. And you know that there has to be a predicate device?

1 A. That is correct.

2 Q. And the predicate device for Recovery was Greenfield and  
3 Simon Nitinol filter?

4 A. I know from prior testimony it's Simon Nitinol filter, but  
5 I'm unsure about the Greenfield, or I can't remember.

6 Q. And in order for a company to get another product on the  
7 market through the 510(k) process, they have to establish that  
8 the device -- the new device they want to sell has to be  
9 substantially equivalent in safety and effectiveness to the  
10 predicate device. You've heard that before?

11 A. Yes, that's correct.

12 Q. So in this case, in order for the Recovery filter to be  
13 legally marketed in the U.S., it would have to have been  
14 substantially equivalent from a safety and effectiveness  
15 standpoint as the Simon Nitinol filter; true?

16 A. As defined by the 510(k) protocol.

17 MR. LOPEZ: Okay. Can we go to the next page, please.

18 So just go down to the very bottom of that sample  
19 identification.

20 BY MR. LOPEZ:

21 Q. I'm only doing this because I'm hoping your Friday  
22 afternoon memory and my Friday afternoon memory is helped a  
23 little bit. Because we're going to see some of these symbols  
24 when we start walking through this.

25 A. Thank you. Yeah, that's helpful.

1 Q. For example, we're going to see some comparisons to the  
2 Cook filter. And when we see TPs, let's -- I'm going to write  
3 that down. TP is Cook, and O is Cordis. RF is Recovery. GT  
4 is the Greenfield. And then this SF is Simon Nitinol. I'm  
5 sure I missed a couple, but I'm not going to walk through every  
6 single one of these.

7 So when we look at these results, we'll be able to see  
8 how the Recovery compared to these other devices.

9 THE COURT: I think you need to be asking questions --

10 MR. LOPEZ: I'm sorry.

11 THE COURT: -- Mr. Lopez.

12 MR. LOPEZ: Let's go to page 6 of the document. And,  
13 Felice, I'm going to ask you to just highlight -- well, first  
14 of all, before you --

15 BY MR. LOPEZ:

16 Q. These are the results, the summary results of the test;  
17 right?

18 A. That is correct.

19 MR. LOPEZ: And can we just highlight the first six  
20 lines of the summary report, the one that ends at SF1-SF10.  
21 There you go. Did we miss one? Oh, five lines, okay.

22 BY MR. LOPEZ:

23 Q. So this doesn't have it on there. I'm not going to have  
24 her put it on the screen, but 37, that's a temperature;  
25 correct?

1 A. That's correct.

2 Q. And is that roughly -- that's Celsius?

3 A. That is correct.

4 Q. And that's roughly human normal body temperature?

5 A. Yes, that's correct.

6 Q. And how about 40 Celsius? Is that roughly 104 degrees in a  
7 human?

8 A. Yeah, roughly.

9 Q. Okay. And was there a reason why you tested this device at  
10 104 degrees?

11 A. We -- all that I can recall is I recall that we set up in  
12 the protocol 37 degrees and 40 degrees. I think 40 degrees was  
13 what it was originally tested at NMT. So I was just doing it  
14 per -- basically because I would write the protocol and so  
15 forth, but then I'd give it to my boss and he'd be like, hey,  
16 this is what we're doing.

17 Q. So the testing that was done at NMT that was used to clear  
18 the Recovery filter was done at 40 degrees?

19 A. I believe so, but I'd have to look at the document to  
20 confirm.

21 Q. So let's look at these results. And we'll talk about that  
22 in a second.

23 Do you see it's the 28 diameter millimeter, that's the  
24 width of the vena cava that was sampled, that it was tested in;  
25 correct?

1 A. The diameter.

2 Q. The diameter.

3 And this test apparatus or what it was tested in was  
4 not like a cadaver IVC. It was actually done on the bench.

5 And I can go to the document. Let me see if I can  
6 refresh your recollection.

7 Silicone tubing with sausage casing in it; right?

8 A. That's correct.

9 Q. And that was being used by the company to simulate the -- a  
10 human vena cava; right?

11 A. That's what we were using to simulate the vena cava for  
12 this bench test, correct.

13 Q. And, of course, the difference between a silicone tube and  
14 sausage casing for testing and a human vena cava is a human  
15 vena cava is a very dynamic vessel; right? It's not going to  
16 stay at 28 millimeters rigid. It's going to be moving  
17 constantly; true?

18 MR. CONDO: Again, Your Honor, I think counsel is  
19 testifying. Can we have a question?

20 BY MR. LOPEZ:

21 Q. Is that true?

22 MR. LOPEZ: I'm sorry.

23 THE COURT: Overruled.

24 THE WITNESS: So the vena cava's definitely more  
25 dynamic than a silicone tube.

1 BY MR. LOPEZ:

2 Q. Okay. Let's look at the results of the 28-millimeter  
3 diameter. And I don't think I've asked you this.

4 28-millimeter diameter was the maximum diameter of a  
5 vena cava that the Recovery filter was indicated to be used in;  
6 true?

7 A. I believe that's the case.

8 Q. And it was tested that way at NMT; right? Do you remember  
9 that?

10 A. I believe it was.

11 Q. Okay. So, and did you also know that NMT, and adopted  
12 by -- later adopted by Bard, used 50 millimeters of mercury as  
13 the migration resistance threshold as to whether or not a  
14 filter failed or passed a migration test?

15 A. That was the D&V testing you're talking about?

16 Q. Yeah. There was --

17 A. That was -- yeah, they established the 50 millimeters of  
18 mercury acceptance criteria for the DV&V, correct.

19 Q. That was the internal product specification for this test,  
20 that if it was 50 or better, you passed; if it was under 50,  
21 you failed?

22 A. That was the specification for the documents that had  
23 acceptance criteria, like the DV&V.

24 Q. Now, I'm jumping ahead a little bit, but later when Bard  
25 started getting advice, including yourself, there were some

1 suggestions that that was -- that threshold was way too low to  
2 test it to see whether or not that really simulated what was  
3 going to happen in a human. True?

4 A. I am not aware of that.

5 Q. So let's just use the 50 millimeter of mercury threshold.

6 In the RF -- again, those are all Recovery filters  
7 that were tested; true?

8 A. That is correct.

9 Q. And just so the jury understands the sampling, there were  
10 ten different samples -- actually, ten plus what, three more --  
11 13 samples?

12 A. That's what it appears to be, yes, correct.

13 Q. And the mean was under 50 millimeters of mercury. True?

14 A. The mean was under 50 millimeters of mercury in this test,  
15 correct.

16 Q. And, in fact, the -- there was a minimum of 32.1 and a  
17 maximum of 64.8. Do you see that?

18 A. That is correct.

19 Q. Now, just because it was the mean didn't mean that there  
20 was only a couple. There could have been a lot -- and we'll  
21 look at that in a second.

22 There were a number of these runs of the test that  
23 were below 50, some of them significantly below 50. True?

24 A. There's definitely some below 50.

25 Q. Now, let me ask you, if Bard in a 510(k) were to submit a

1 test like this and they told FDA that, by the way, our minimum  
2 threshold for migration safety and performance is  
3 50 millimeters of mercury but we're only getting 47.5, would  
4 that have had an influence on whether or not --

5 MR. LOPEZ: I'm going to move -- I'm not going to ask  
6 that question, Judge.

7 Let's go to the next one, because I want to get to the  
8 Simon Nitinol filter.

9 BY MR. LOPEZ:

10 Q. Do you see the difference between the Simon Nitinol filter  
11 at normal human body temperature, 76.3?

12 A. Yes, I do.

13 Q. And you see the minimum there was 65 to 105.8. Do you see  
14 that?

15 A. Yes, I do.

16 Q. That means -- does that mean that every single Simon  
17 Nitinol filter that was tested was at 65 or better?

18 A. That would be correct, yes.

19 Q. And, in fact, if you look at the difference between the  
20 Recovery filter and the Simon Nitinol filter, just for  
21 migration resistance, in a 28-millimeter tube the Simon Nitinol  
22 filter is virtually twice more resistant to migration than the  
23 Recovery filter. True?

24 A. Yep. Almost.

25 Q. Is that -- was that Bard's definition of substantially



1 equivalent, that they could be that far apart but yet have the  
2 same safety and effectiveness?

3 A. Again, I'd have to look at the design verification  
4 validation protocol. Because that would outline the details  
5 and acceptance criteria.

6 Q. Okay. Now, let's look at the next three lines.

7 And NMT, do you see where I am there? NMT?

8 A. Yes, I do.

9 Q. Okay. And NMT, what does that mean? We didn't talk about  
10 that earlier when we were making our notes.

11 A. Hmm. Trying to recollect here.

12 Q. Well, NMT was --

13 A. Yeah, that was -- oh, that was NMT. It's probably -- I  
14 would think it's -- it might have been NMT. I'm not sure if  
15 NMT -- filters from NMT.

16 Q. In other words, maybe they were manufactured at NMT?

17 A. Potentially, yeah. I'm having difficulty to recall, but...

18 Q. Okay. And then RF was the Recovery filter?

19 A. That is correct.

20 Q. And SF, again, is the Simon Nitinol filter; correct?

21 A. That is correct.

22 Q. And this is 104 degrees; right?

23 A. That is correct.

24 Q. And this is the test that NMT ran, as far as you recall;  
25 true?

1 A. As far as I recall, true.

2 Q. And it passes this test; right? At least if you use the  
3 50 millimeters of mercury as the minimum safety threshold, the  
4 NMT devices and the Recovery devices are both over 50. True?

5 A. They're all over 50, correct.

6 Q. So if you're 104 degrees and you've got one of these  
7 filters, you've got a little better chance of migration  
8 resistance than if you are putting these in patients that are  
9 in normal body temperature; is that fair to say?

10 A. I'd say it's fair to say it looks like the migration  
11 resistance goes up slightly. Correct.

12 MR. LOPEZ: Okay. Let's go down to, please, the --  
13 and before you do that, let's -- can we just look at that whole  
14 first box? Before we go down to the 30-millimeter tube,  
15 please, Felice.

16 MS. REED ZAIC: You have to be clear.

17 MR. LOPEZ: Just the 28 -- just where it says 28 tube  
18 diameter. I just want the box with the 28 tube diameter. I'm  
19 sorry. That whole big box. The top one, yes. Thank you.

20 BY MR. LOPEZ:

21 Q. So against all of these competitors, GT was the Greenfield,  
22 O was Cordis, and TP was Cook. Do you see that?

23 A. Yes, I do.

24 Q. And would you agree with me that the Recovery filter is  
25 significantly less in migration resistance than every other

1 device that Bard tested except for whatever TP is?

2 A. It appears it's a lower mean than the TP. I mean -- excuse  
3 me. It appears that the Bard Recovery is lower than all these  
4 other filters, with the exception that it appears to be higher  
5 than the TP.

6 MR. LOPEZ: Okay. And, Felice, could you go down to  
7 the middle box that has 30 as the tube diameter.

8 BY MR. LOPEZ:

9 Q. Now, why is it being tested in a vena cava, a simulated  
10 vena cava that's 30 millimeters -- I'm sorry, 30 millimeters  
11 wide?

12 A. Because I was asked to test in a 30-millimeter cava. Our  
13 silicone tube, I should say.

14 Q. Did they tell you why?

15 A. I don't know if -- recollect if we went into the details as  
16 to why, but I was definitely asked to test at that.

17 Q. Now, as an engineer, are you familiar with the phrase  
18 testing to worst-case scenario?

19 A. Yes, I am.

20 Q. And are you -- were you also familiar when you were running  
21 these tests that Bard had determined that the vena cava does  
22 not stay static but actually has -- it's actually pretty common  
23 for the vena cava to expand and contract every day, just normal  
24 human living? Sometimes if you cough too hard, it can expand.  
25 Were you aware of that?

1 A. I'm not sure, you know, if I was completely aware of that  
2 or not. Again, I was just pulled into the test.

3 Q. Okay. So in a 30-millimeter diameter, in other words, if  
4 this was tested -- let's say you put it in a 25-millimeter  
5 diameter vena cava. If it were to expand 5 millimeters and get  
6 to 30 -- I think I did that math right, 25 to 30 --

7 A. Yeah, yeah.

8 Q. -- you would -- you can test it to see what -- how the  
9 filter might behave. At least in the lab you could do that;  
10 right?

11 A. Yeah, that sounds reasonable.

12 Q. And then, again, this is -- this is all 104 degrees; right?  
13 This summary report. Everything else that we're going to be  
14 looking here is at 104 degrees temperature?

15 A. That is correct.

16 Q. But even at 104 degrees, if the vena cava expands just a  
17 few millimeters after it's placed in the human body, it fails  
18 just the mean number, the 50-millimeter mercury migration  
19 resistance, by 20 percent, more than 20 percent; right?

20 A. It looks that way, yes.

21 Q. And the Simon Nitinol filter is still -- even though the  
22 Simon Nitinol filter at the time was indicated for a smaller  
23 vena cava, it was better than the Recovery filter by almost  
24 about two and a half times in migration resistance in a  
25 30-millimeter test tube. True?

1 A. Yes. It looks higher.

2 Q. And then if we go down to 32, in the next box,  
3 32 millimeters --

4 And, by the way, we're not talking about very much;  
5 right? What -- in inches, how much is 2 millimeters?

6 A. I don't know, on the top of my head, how much that is. I'd  
7 have to do the math.

8 Q. Well, how many millimeters in an inch? Let's do it  
9 together.

10 A. I don't know off the top -- I mean, what is it, 25?

11 Q. Let's go with that.

12 A. Yeah, okay.

13 Q. So 2 millimeters would be about 1/12 of an inch. Can we  
14 agree on that?

15 A. I guess so.

16 Q. Okay. So that's just moving -- just the vena cava moving  
17 2 millimeters, like a 12th of an inch. Okay?

18 A. Okay.

19 Q. So you tested it now moving 1/6 of an inch against the  
20 Simon Nitinol filter; and, again, at 104 degrees, it was 34  
21 versus 79 for the Simon Nitinol filter. Correct?

22 A. Correct.

23 Q. And then O, the Cordis device, which was a combination  
24 retrievable/permanent device; true?

25 A. Correct.

1 Q. It was 86. It was even a little better than the Simon  
2 Nitinol.

3 Do you see that?

4 A. Yes, I do.

5 Q. Let me ask you, sir, were these results shared with anyone  
6 outside of Bard, the results of these tests?

7 A. I do not know. Obviously these would be shared with Rob  
8 Carr, my boss, and some of those others on the team, but I  
9 don't know if these results were or not.

10 Q. This was in -- I believe in March of 2004. Is that right?

11 A. I believe so.

12 Q. And at that time, was there any slowdown or halt on the  
13 marketing effort by Bard?

14 A. Not that I'm aware.

15 Q. Did they change their IFU or their warnings or their  
16 marketing material to reflect that Bard was failing its own  
17 bench testing on migration resistance?

18 A. So this bench testing had no acceptance criteria, if you  
19 look at the protocol.

20 Q. Okay. But it was consistent -- the fact that it was  
21 failing, it was migrating and didn't have good migration  
22 resistance, had already been seen in human beings in a clinical  
23 pilot study and in the open market. So you knew this device  
24 could migrate; right?

25 A. Well, the challenge is some of these filters were used over

1 and over.

2 Q. We'll get to that.

3 A. Okay.

4 MR. LOPEZ: Let's look at 2063, please.

5 Your Honor, I'd like to offer 2063 into evidence.

6 THE COURTROOM DEPUTY: It's admitted.

7 THE COURT: It's already in evidence.

8 MR. LOPEZ: Oh, it is? Okay.

9 And can we go to the very first page. Is there a  
10 cover email for this on page 1? Okay. There we go.

11 BY MR. LOPEZ:

12 Q. Okay. So this is you sending an email with the results of  
13 the migration resistance testing you just ran; correct?

14 A. I'm not sure -- so this just says: I have attached the  
15 most current results.

16 I don't know if this was the study we were just  
17 looking at or another study.

18 Q. We can figure that out if you just go to the next page.

19 A. Sure.

20 Q. The very next page.

21 And these are all the individual runs that were done  
22 and the summary we just looked at. Would you agree with me?

23 A. Yeah. We might need to compare this data to the data that  
24 was in the report. I don't know if that's possible.

25 Q. Okay. If -- let's -- all right. Actually, maybe it's not,

1 so let's look at the mean of the -- of this report. Page 2 of  
2 the exhibit.

3 And, again, if you look at the average, it's 45.2 for  
4 the Recovery filter at normal body temperature. See that?

5 A. Yes, I do.

6 Q. And then at 104 degrees, it's 51.5. Do you see that?

7 A. Not yet, but -- yeah, I do now. Thank you.

8 Q. Pretty similar to what we just looked at in another test.  
9 Correct?

10 A. I think so.

11 Q. And then if you go to the next page, and that was in a --  
12 that was a 28-millimeter tube again; right?

13 A. Yeah. Can you flip it back one more time, just so I can --

14 Yes. Thank you.

15 Q. And then the next page are the results for the Simon  
16 Nitinol filter, again, under the same conditions that the  
17 Recovery filter was tested?

18 A. Yes.

19 Q. And we have a 76.3, an 89.1.

20 Do you see that?

21 A. I do.

22 Q. All right. And then if you go to page 5 and 6 -- let's  
23 look at 5 first.

24 Do you see, that's VT? That's a competitor, VenaTech.

25 You have the results for VenaTech. You have the results for



1 Greenfield. You have the results for Cook. And all the other  
2 competitors that are on the market. True?

3 A. True.

4 Q. And let's go to page 10 of this exhibit.

5 And the OptEase was a competitor. It had both  
6 retrievability and permanent indication; correct?

7 A. Correct.

8 Q. And this shows 136.6 resistance in the tests that you  
9 subjected the Recovery to, which was almost three times the  
10 migration resistance of the Recovery filter. Is that true?

11 A. True.

12 MR. LOPEZ: Can I publish this to the jury, Your  
13 Honor? Just this last page is fine.

14 THE COURT: You may.

15 MR. LOPEZ: Thank you.

16 And can we just go back to page 2, Felice, please.  
17 And you just -- okay, you have it. Page 2, yeah.

18 BY MR. LOPEZ:

19 Q. You have highlighted there the mean that we just talked  
20 about, 56 point -- 45.2 and then 51.5 for the Recovery. Then  
21 the next page, 76.3.

22 MR. CONDO: Your Honor, can we have a question,  
23 please?

24 THE COURT: Yes, we need to proceed by question and  
25 answer.

1 BY MR. LOPEZ:

2 Q. Do we have 76.3 and 89.1 on page 3 of this exhibit?

3 A. Yes.

4 THE COURT: Is that a question?

5 BY MR. LOPEZ:

6 Q. Yeah, do we have it --

7 A. Yes.

8 Q. Is that what we see here?

9 A. Yes.

10 Q. And that relates to the Simon Nitinol filter; correct?

11 A. That's correct.

12 Q. Okay. So this temperature issue, does raising the  
13 temperature on a material like Nitinol actually cause it to  
14 expand?

15 A. It should.

16 Q. And so there might be a difference in what the size of the  
17 Simon -- I'm sorry, of the Nitinol in these filters at  
18 104 degrees versus a normal human temperature, right, 98.6?

19 A. Are you talking about -- I'm not sure about the -- you're  
20 talking about the size?

21 Q. The expansion, yes.

22 A. I don't know if it would expand further out or not. I  
23 would talk to Andre about that.

24 Q. Did you send all these results of the tests we just talked  
25 about to Mr. Carr?

1 A. Yes.

2 Q. Did you send them to everybody on that team that we just --  
3 we saw earlier, Mr. Uelmen, Ms. Hudnall?

4 A. So I don't know -- if you go back to the cover letter, it  
5 should say everybody I shared it with.

6 So I definitely shared it with those people there, Rob  
7 Carr, Brian Hudson. I'm not sure, this specific test right  
8 here, because I'm not -- doesn't say where it's coming from  
9 exactly, if it went to the others.

10 Q. Did you express any personal concern yourself when you saw  
11 the results of this test that the Recovery filter was not  
12 passing even its bench testing threshold for migration?

13 A. So I did not exhibit any concern.

14 Q. Okay. Was it -- do you know if Mr. Carr or anyone else,  
15 when you were discussing these tests, expressed any concern  
16 about the findings?

17 A. I don't recall. Again, this was -- this testing had no  
18 acceptance criteria, so...

19 Q. Did the performance of the Recovery filter get any better  
20 out in the open U.S. market after these tests were performed?

21 A. Not that I'm aware of.

22 Q. In fact, it got -- didn't it get progressively worse?

23 A. Not that I know of.

24 Q. You don't know about the fact that the Recovery filter was  
25 causing some fairly significant injuries, catastrophic

1 injuries, even after these tests were run?

2 A. I knew that there were some different complications in the  
3 field from past prior -- you know, past testimony. But in  
4 recalling, you know, I wasn't tracking the filter. My job was  
5 to test it and to work on the jugular delivery system, so I'd  
6 have to defer to Rob to that.

7 Q. But what you do know is that while all of this testing was  
8 going on and discussions about redesigning the Recovery filter,  
9 it was business as usual in the marketing and sales department  
10 with this device. True?

11 A. As far as I recall.

12 Q. And were you at all involved in discussing, you know, maybe  
13 conceptually how you might improve the design of the Recovery  
14 filter to at least minimize if not eliminate some of the  
15 serious injury and patient safety problems that were being  
16 experienced by the Recovery filter?

17 A. Again, my job was the jugular delivery system. I got  
18 called into testing. Andre is the person who is responsible  
19 for designing and innovating on the filter.

20 Q. We're going to go over a couple more tests.

21 A. Sure.

22 Q. Probably won't do it right now because we're getting close  
23 to the break, but let me ask you --

24 THE COURT: We're going to go till 2:45.

25 MR. LOPEZ: Okay.

1 BY MR. LOPEZ:

2 Q. Once you ran the tests, and the ones we've already done and  
3 the ones that -- when I say "done," the one you and I have  
4 already discussed and some of the ones coming up -- did you  
5 have any further involvement in meetings that took place where  
6 the results of those tests were discussed?

7 A. I would -- you know, again, I think I would have had  
8 involvement to some degree, but, you know, that was 13 to  
9 15 years ago. So most of the stuff I'm recalling today is just  
10 thankfully because we have this documentation in front of me.

11 Q. When you delivered the results of these tests, the ones we  
12 just went through --

13 A. Yes.

14 Q. -- and you gave them to those who were your supervisors  
15 like Mr. Carr -- and when you say Andre, you're talking about  
16 Mr. Chanduszko; right?

17 A. That's correct, yeah.

18 Q. When you gave these to them, did they say to you that: You  
19 need to rerun these tests because we don't like the way it was  
20 run; the protocol was wrong; we should have used a different  
21 approach to this?

22 Anything like that?

23 A. Not that I recall.

24 Q. In fact, you went on to test these same devices and doing  
25 the same comparisons in other potentially worst-case scenarios,

1 like with the legs crossed and maybe a hook, one, two, three,  
2 four, five, six, not attached to the vena cava wall; correct?

3 A. That is correct, yeah.

4 Q. And do you recall that the reason you were doing that is  
5 because that was anticipated real-life situation with these  
6 devices, that you can either have a hook that breaks and now  
7 you don't have an attachment of one of the six legs or one --  
8 you know, one just breaks and it's not there. Right?

9 A. I was testing it because I was told to test it, and I did.

10 Q. Did you think that doctors, hospitals, and patients would  
11 want to know that your company was selling a device and that  
12 you're questioning the testing and you're still testing it to  
13 see whether or not it's performing safely from a migration  
14 standpoint?

15 MR. CONDO: Foundation. 602.

16 THE COURT: Sustained on foundation.

17 BY MR. LOPEZ:

18 Q. Well, you're an engineer when you were doing this; right?

19 A. That is correct.

20 Q. And you made -- and I think engineers have a code with  
21 respect to their conduct and their principles; right?

22 A. We -- yeah. I mean, we -- well, I mean, what do you mean  
23 by "code"?

24 Q. Well, I mean, engineers should have a high threshold of the  
25 way they design, test devices that potentially are going to go

1 in human beings and if not designed and tested properly could  
2 cause some serious harm?

3 A. Yeah, we want to -- I mean, our job is to make the most  
4 safe and effective device to help physicians and help patients.

5 Q. When you saw the results of this test, knowing that the  
6 device was already on the market, knowing that under reasonably  
7 foreseeable human conditions this test was not even performing  
8 in the laboratory, did it cause your engineering sense, your  
9 training as an engineer, to question whether or not this device  
10 should be on the market until Bard brought that device back in  
11 to see if they could fix that?

12 A. I did not question it because, again, this is the protocol.  
13 There's no acceptance criteria. Filters are reused. There's  
14 different things. Rob Carr would be better to speak to that.

15 Q. How long did you stay on this team?

16 A. I left, I believe it was June of 2005.

17 Q. Okay. Oh, so you were on it for -- almost till Bard  
18 stopped selling Recovery; right?

19 A. I'm not sure when we stopped selling it.

20 Q. Well, would you have been at meetings when there were  
21 discussions about the ongoing serious problems that Bard was  
22 having with the Recovery filter?

23 A. I was not part of those meetings that I recall.

24 Q. Did you ever get any health hazard evaluations during that  
25 period of time?

1 A. I never was involved with that.

2 Q. So was that just a select group of people that were able to  
3 get access to that kind of information?

4 A. You'd have to ask Rob Carr. Again, I was not pulled into  
5 that -- those types of meetings, I guess. I mean, what  
6 happened is I was working on a jugular delivery system. They  
7 pulled me in to do testing. That was my -- you know, my main  
8 focus was developing the jugular delivery system.

9 Q. So after you had done all this -- the testing that we've  
10 been talking about on the Recovery filter, there was another  
11 few months that went by until you stopped working on the  
12 Recovery. I think you said in the middle of 2005. What were  
13 you doing during that period of time?

14 A. During the -- you know, that period of time, what I can  
15 recall is my main -- I was developing the jugular delivery  
16 system. So we were working on molding, catheters, you know,  
17 the stop mechanism, all for the jugular approach.

18 MR. LOPEZ: Let's look at Exhibit 79, please.

19 Your Honor, I'd like to move Exhibit 79 into evidence.

20 MR. CONDO: No objection, Your Honor.

21 MR. LOPEZ: May I publish?

22 THE COURT: Admitted.

23 (Exhibit No. 79 admitted into evidence.)

24 MR. LOPEZ: Sorry, Your Honor. May I publish?

25 THE COURT: You may.



1 BY MR. LOPEZ:

2 Q. So this is another test that I think you helped design and  
3 oversaw. True?

4 A. That is correct.

5 Q. And this document we're looking at, is this the product of  
6 your input and your writing?

7 A. Yes. It would be the product of my input. Of course, my  
8 boss would review it and make edits.

9 Q. Okay. This was another migration resistance test; correct?

10 A. This appears to be a protocol.

11 Q. If you go to page 2, the purpose of this test was to  
12 further the characterization of Recovery in relationship to  
13 migration resistance. True?

14 A. True.

15 Q. Didn't you find it odd that they're still trying to figure  
16 out the migration resistance issues with this device on the  
17 bench and they're -- but they're now selling it into the open  
18 marketplace?

19 A. To be honest with you, not really, because we're always  
20 trying to innovate and develop products further and further.  
21 So, you know, this is something we continually do in the  
22 medical device industry --

23 Q. Are you saying --

24 A. -- we try to make things better.

25 Q. I'm sorry. I apologize.

1 A. Go ahead. Sorry.

2 Q. Are you saying that these testing had nothing to do with  
3 what was happening in real-life human beings who were getting  
4 the Recovery filter?

5 A. I'm saying obviously there was that special design review  
6 called. They were asking me to do that testing, but in regards  
7 to the specifics of why, I'd have to leave that to Mr. Carr to  
8 talk about.

9 Q. So are you speculating when you're saying that this just  
10 was normal, everyday, we're trying to go to the next level type  
11 testing?

12 A. Oh, that could be -- yeah, that could be potentially true.

13 Q. Because if I were to ask you if there were some real live  
14 human safety issues that caused this design review meeting and  
15 all these tests afterwards, you wouldn't know about that; true?

16 A. That is correct.

17 Q. Okay. So let's look at -- this is the test -- yeah, this  
18 is when you were going to test it with one hook and the legs  
19 twisted. Correct?

20 MR. LOPEZ: And let's go to page 7.

21 THE COURT: You need to let him answer the question,  
22 Mr. Lopez.

23 MR. LOPEZ: I'm sorry.

24 MR. CONDO: Thank you, Your Honor.

25 THE WITNESS: Correct.

1 MR. LOPEZ: Can we go to page 7, please?

2 BY MR. LOPEZ:

3 Q. And we talked about this earlier.

4 So this is what Bard used to simulate a human vena  
5 cava, silicone tubing; right?

6 A. Correct.

7 Q. And a sausage casing.

8 And then certain pressures would be applied to see  
9 what the migration resistance was of this device in that  
10 environment. Correct?

11 A. Correct.

12 Q. And let's go to 2065, please. And page --

13 Let me ask you this: You're familiar with this test;  
14 right? This is the test that we just talked about in the  
15 protocol just before it; correct?

16 A. That's correct.

17 MR. LOPEZ: Your Honor, I'd like to offer 2065.

18 MR. CONDO: No objection, Your Honor.

19 MR. LOPEZ: May I publish?

20 THE COURT: It is admitted, and you may publish.

21 (Exhibit No. 2065 admitted into evidence.)

22 BY MR. LOPEZ:

23 Q. Can we go to the second page of this exhibit?

24 Okay. See where it says "Recent field activities"? I  
25 was just asking you about that, so let's look at this on

1 page 2, in the middle, 2.0, that middle paragraph.

2 "Recent field activities." Could you read that,  
3 please, out loud?

4 A. Yep.

5 "Recent field activities indicate that migration  
6 failures have been reported for the RF product. Therefore,  
7 further testing of this specific characteristic is warranted."

8 Q. Does that help refresh your recollection that this just  
9 wasn't a routine --

10 A. Yes, it does.

11 Q. -- situation?

12 That there were actually some things going on in the  
13 open marketplace that was of concern; true?

14 A. According to this, it says recent field activity, so  
15 something was going on.

16 Q. Well, if you look at the next paragraph, there's that same  
17 sentence we read -- we saw earlier. Do you see that? A  
18 special design review --

19 A. Yes, I do.

20 Q. -- to gain a further understanding of the, quote, design  
21 elements of this product.

22 True?

23 A. Correct.

24 Q. And then if you look where it says "Migration resistance,"  
25 what does that -- read that entire sentence.

1 A. Sure.

2 "Migration resistance was one of the critical elements  
3 identified for review."

4 Q. And by the way, the words that we're reading in here are  
5 your words because you prepared this document; right?

6 A. They're partially my words, because I have other people  
7 that review it and then I make changes.

8 Q. And then you would -- before it was submitted to others,  
9 you would review it; and the final product would be something  
10 that you reviewed, potentially edited, and approved?

11 A. So the team would work together and, you know, we'd all  
12 sign off on this document. But ultimately, you know, certain  
13 changes could be made on this document, like from Rob that  
14 would say, hey, we got to change this or whatnot so -- but,  
15 yes, we all reviewed it together.

16 Q. Page 3, please. Under 6.0. See where I am, that first  
17 bullet point?

18 So you record when you have difficulties or some  
19 issues during the course of the test? That's something you do  
20 in this report?

21 A. Correct.

22 Q. And so one of the problems you were having was that the  
23 simulated sausage casing clots were getting caught on the rough  
24 transition in the 1-inch PVC piping.

25 Did I read that correctly?

1 A. That is correct.

2 Q. And so that's something you had to deal with as you were  
3 running these tests?

4 A. What's that again? Sorry.

5 Q. That's something you had to deal with that --

6 A. Yeah. I mean, sometimes when we're running the tests  
7 and -- things happen, and we try to mark down deviations and  
8 capture, hey, what happened.

9 Q. Okay. Now, I'm going through this, and I'd ask you to do  
10 the same, and ask you if there was any testing done at  
11 37 degrees.

12 A. Is that it?

13 Q. Was there any testing done?

14 A. Not that I saw.

15 Q. Do you have any recollection as to why you would just test  
16 under the conditions of 104 degrees and not under the  
17 conditions of a normal body temperature?

18 A. I do not have any recollection.

19 Q. And let's look at page 5 of this exhibit.

20 MR. LOPEZ: And, Felice, if you could go down to the  
21 very bottom, under the section that has the 28-millimeter tube  
22 and 1 through 6, just that box right there.

23 BY MR. LOPEZ:

24 Q. Just so we're clear, this was a test with one leg detached  
25 from the side of the vena cava -- well, sausage casing. True?

1 A. Was it a leg or a hook?

2 Q. I don't know what -- can you tell me?

3 A. Can you pan out? It would say right there.

4 A hook. On the top, it says number of hooks removed.

5 So it would have been just the hook.

6 Q. So if a hook had broken off like what happened in the Asch  
7 study, or just for some reason got detached, this would  
8 simulate what might happen under those conditions; true?

9 A. So this would simulate what happens in this particular  
10 bench test if the hook's removed.

11 Q. And with one hook removed at 104 degrees in a 28-millimeter  
12 tube, the migration resistance of the Recovery filter had a  
13 mean of 33; correct?

14 A. That is correct.

15 Q. And there wasn't one sample that was greater than 41.7;  
16 true?

17 A. That was -- correct.

18 Q. And, again, 50 millimeters of mercury was -- the company  
19 had decided was going to be the threshold for safety from a  
20 migration resistance standpoint in the laboratory; true?

21 A. So that was the threshold of safety for the control DV&V  
22 testing and those tests. This had no acceptance criteria.

23 Q. Now, later when there were discussions about raising the  
24 threshold to something higher than 50, say 70 or 80 or -- in  
25 that area, even a hundred, were you included in those

1 discussions?

2 A. I was not.

3 Q. Were you ever asked to do any of these tests where the  
4 minimum threshold for pass or fail was 70?

5 A. Not that I recall.

6 Q. Okay. Can we have 1369, please.

7 Mr. Tessmer, this is an email from you in March of  
8 2004; correct?

9 A. That is correct.

10 Q. And you wrote this memo?

11 A. Yes, I did.

12 MR. LOPEZ: And, Your Honor, I'd like to offer 1369.

13 MR. CONDO: No objection, Your Honor.

14 THE COURT: Admitted.

15 (Exhibit No. 1369 admitted into evidence.)

16 MR. LOPEZ: May I publish?

17 THE COURT: Yes.

18 BY MR. LOPEZ:

19 Q. Okay. This is -- there's a new name here, Charlie Benware.  
20 Who's Charlie?

21 A. I think he was in the manufacturing department, but I might  
22 be incorrect on that.

23 Q. And who's Ed Fitzpatrick?

24 A. He would have been at the manufacturing facility.

25 Q. So what was the issue here with this memo that you wrote?



1 A. Is there something specific you want me to read here?

2 Q. Yeah, I mean, what -- there had to be a reason why you  
3 wrote this. Without us reading it, can you just explain to the  
4 jury?

5 A. It looks like we did -- the issue was it looks like we were  
6 trying to qualify a wire of some sort. And when I ran the  
7 testing, all the different things I was trying to test, it  
8 looked like there were some that fell below the 50 millimeters  
9 of mercury acceptance criteria.

10 And then I noted, I guess later on, that something's  
11 wrong here. Something's going on with the testing, because we  
12 just tested these and they all passed. So that's kind of a  
13 synopsis of the whole email.

14 Q. All right. And what was --

15 THE COURT: We're going to break at this point. We  
16 will resume at 3:00 o'clock, ladies and gentlemen. We'll  
17 excuse you at this time.

18 (Recess taken, 2:45 p.m. to 3:00 p.m.)

19 THE COURT: You may continue, Mr. Lopez.

20 MR. LOPEZ: Thank you, Your Honor.

21 BY MR. LOPEZ:

22 Q. Mr. Tessmer, let's just look at 1369.

23 And 1369 was -- involved some actual -- actually,  
24 fresh filters that were taken off the assembly line that you  
25 were concerned were not passing some of the tests; is that a

1 fair statement?

2 A. This was from what, 1369?

3 Q. Yeah, Exhibit 1369. It's the --

4 A. Yeah, I'm not -- go ahead.

5 Q. It's the Starguide filter migration test results.

6 A. Got it.

7 Yeah, I don't know if they -- I would imagine they  
8 would be fresh filters, but I don't recollect exactly, and I'm  
9 not sure if it says it in the document here. That's what I'm  
10 looking at.

11 Q. This regards another migration test?

12 A. Yes. Migration testing was performed on these.

13 MR. LOPEZ: And if you -- Felice, if you could give us  
14 that middle -- the fourth paragraph, "You will quickly notice."

15 BY MR. LOPEZ:

16 Q. Do you see that?

17 A. Yes, I do.

18 Q. "That there were values below 50 millimeters of mercury  
19 acceptance criteria for all three Starguide manufacturing  
20 lots."

21 Do you see that, sir?

22 A. Yes, I do.

23 Q. And these were filters that were manufactured using the  
24 current supplier?

25 A. That's what it says here, correct.

1 Q. And then if you go down to the next paragraph, you were  
2 trying to do an analysis of this situation where you had these  
3 fresh filters not passing the resistance testing?

4 A. We were -- I think we were taking filters and testing them  
5 against each other from various suppliers, it appears, and they  
6 were below the 50 millimeters of mercury.

7 Q. So, but you also wanted to see if maybe it had something to  
8 do with the sausage casing in the next paragraph; right? Right  
9 there at the bottom?

10 A. Where is it?

11 Q. The next paragraph down.

12 A. Oh. Okay, yep, I see it. Correct.

13 Q. Okay. And then so what you did there is you inspected the  
14 sausage casing, that last sentence. It says: The sausage  
15 casing was packaged the same and came from the same supplier.

16 Do you see that?

17 A. Yes, I do.

18 Q. It had the same appearance, feel, and odor as the previous  
19 casing.

20 Do you see that?

21 A. Yes, I see that.

22 Q. So it seemed like it probably wasn't the sausage casing;  
23 right?

24 A. Yep, possibly, yeah. That's what that's saying right  
25 there. That's what the operators noticed.

1 Q. Did you ever figure out what it was? Was it -- that caused  
2 those -- the tests to be below 50 millimeters of mercury?

3 A. Not that I'm aware.

4 Q. So you thought it might be the Nitinol supplier or the  
5 sausage casing?

6 A. I think I said -- let me see here.

7 I think I -- well, I stated here in the middle  
8 paragraph: This points to the fact there was some issue with  
9 the migration resistance testing.

10 Q. Okay. All right. Let's go to Exhibit 2068, please.

11 And this was an email from Mr. Carr to you; right? In  
12 June of 2004?

13 A. That's correct.

14 MR. LOPEZ: I'd like to offer 2068 into evidence at  
15 this time, Your Honor.

16 MR. CONDO: No objection, Your Honor.

17 THE COURT: Admitted.

18 (Exhibit No. 2068 admitted into evidence.)

19 MR. LOPEZ: May I publish?

20 THE COURT: You may.

21 MR. LOPEZ: Thank you.

22 BY MR. LOPEZ:

23 Q. Now, this -- let's just go to page 2 of this exhibit.

24 Let me just ask you this: Is this email between you  
25 and Mr. Carr -- actually, if you look at the -- on the first

1 page, Mr. Chanduszko is now involved in -- was originally  
2 involved in the discussion with Brian Hudson.

3 Do you see that?

4 A. Yes, I do.

5 Q. Okay. And was this -- looks like they're sending you or --  
6 some information about potential changes in the design of the  
7 Recovery filter to take care of some of these migration  
8 problems.

9 Would that be a fair statement?

10 A. It looks like they got me involved in a design of  
11 experiments, correct.

12 Q. And what does DOE mean?

13 A. Design of experiments.

14 Q. So there's no question that the Recovery filter -- there  
15 was activity to look at how to redesign the Recovery filter to  
16 take care of some of these migration and fracture issues; true?

17 A. Well, there's always activity to innovate, true.

18 Q. And 1023, is that -- are you familiar with that document?

19 A. I believe I've seen this in prior testimony.

20 MR. LOPEZ: I'd like to offer 1023 into evidence, Your  
21 Honor.

22 MR. CONDO: No objection, Your Honor.

23 THE COURT: Admitted.

24 (Exhibit No. 1023 admitted into evidence.)

25 MR. LOPEZ: May I publish?

1 THE COURT: Yes.

2 BY MR. LOPEZ:

3 Q. Now, sir, this is called a Summary of Design Modifications.  
4 True?

5 A. That's what it says, correct.

6 Q. And these were modifications that were being made to the  
7 Recovery filter to create the G2 filter; correct?

8 A. It appears to be, correct.

9 Q. The Recovery filter was the platform, basically, for  
10 whatever changes were going to be made to the next-generation  
11 filter known as the G2 filter; correct?

12 A. It appears so.

13 Q. Did you do any of the testing to see how the wider leg span  
14 on the filter would affect the performance or -- I'm sorry --  
15 affect potentially increasing the potential for perforation in  
16 the -- on the vena cava with the G2 filter?

17 A. I don't recall. I know I did that -- that prior document  
18 you showed, the DOE, I must have -- they got me involved,  
19 because I was more expert in the DOE stuff, to potentially set  
20 up some runs. But I don't recall, myself, being involved in  
21 that.

22 Q. How much farther were you involved in these design changes  
23 that are described in Exhibit 1023?

24 A. Pretty much not at all. I mean, my involvement was more  
25 so, you know, to set up the DOE and then the biggest thing was

1 I believe, if I recall correctly, we started working on how to  
2 put this in a jugular delivery system.

3 MR. LOPEZ: Could we go to page 2 of 1023, please?

4 Can you blow that up? Thank you.

5 BY MR. LOPEZ:

6 Q. And these talk about the G2 filter and the summary of some  
7 of the things that were going to be changed on the G2 filter.  
8 Is that a fair statement?

9 A. That's what this document says.

10 Q. For example, wider leg span, longer arms, things like that?

11 A. That's what it says.

12 Q. Do you know how any of these changes were going to affect  
13 the stability of the G2 filter once implanted in the vena cava?

14 A. I'd definitely refer to Andre for that.

15 Q. Do you know how any of these changes that were being made  
16 to the Recovery filter was going to affect the ability -- the  
17 strength of the hooks and the arms on the G2 filter from  
18 fracturing?

19 A. I will say from the -- that prior document you had up, that  
20 I did say in the document, because I just read it, that  
21 increasing the -- I believe it was the hook diameter increases  
22 the migration resistance, I believe.

23 But if you pull that up, I can be for sure -- I can  
24 tell you for sure.

25 Q. Now, this radial -- the wider legs was meant to have

1 stronger radial force against the wall of the vena cava to keep  
2 it in place?

3 A. I do not know if that's true or not.

4 Q. Do you know what tests were run to confirm whether or not  
5 any of these changes were going to create maybe different  
6 complications with the G2 filter that didn't exist in the  
7 Recovery filter?

8 A. I wasn't involved in any of the testing as far as I recall,  
9 except the migration testing that I was pulled into.

10 Q. And the idea was to make the G2 filter safer than the  
11 Recovery filter; right?

12 A. I believe it was to make some design modification to  
13 improve and innovate and make a better design.

14 Q. Were you involved in, like, discussing what the new design  
15 should be?

16 A. Not specifically that I recall.

17 Q. Do you know if any tests were run to see whether or not the  
18 design of the G2 on the Recovery platform was going to  
19 introduce new and different and maybe even as serious injuries  
20 as were being caused by the Recovery filter?

21 A. I'm sure that there was testing done, but again, I wasn't  
22 involved with those tests.

23 Q. Did the Recovery filter stay on the market until the G2 was  
24 launched?

25 A. I would have to look at documentation to be for sure. I am



1 not sure.

2 Q. Other than what we just saw, this memo between you and  
3 Mr. Carr, I think Mr. Chanduszko was on it, did you have any  
4 further involvement in the G2?

5 A. Not that I'm aware of.

6 Q. So who ran the tests on the G2 before it was launched if  
7 not you?

8 A. So, again, I was pulled in with the Recovery filter for  
9 sure for different migration testing, but there was all kinds  
10 of other testing that was performed on that filter besides that  
11 that I was not involved with.

12 I believe, you know, I think that would be Andre and  
13 the quality department. That's who you'd want to probably talk  
14 to about that.

15 Q. Do you know if during the time that you were engaged in  
16 conversations with Mr. Chanduszko and Mr. Carr and maybe others  
17 regarding the Recovery filter, that maybe the company ought to  
18 do a long-term clinical trial for safety and effectiveness  
19 before they launched the G2 because of the problems they had  
20 had with the Recovery filter after having not done that?

21 A. I was not involved in any of that.

22 Q. Did you ever recommend that, as an engineer who may have  
23 been concerned about the findings on your tests about the  
24 Recovery filter?

25 A. I didn't ever -- I never recommended that.

1 Q. Were your -- the findings that you had on the bench testing  
2 we just went through consistent with what was happening in real  
3 human beings when it came to migration?

4 A. I can't answer one way or another because I don't have all  
5 the data.

6 Q. So after they gave you that initial data that led to these  
7 tests, they didn't keep you apprised of all the additional  
8 catastrophic events that happened when the company chose to  
9 leave the Recovery filter on the market?

10 MR. CONDO: Objection, Your Honor.

11 THE COURT: Sustained.

12 THE WITNESS: I do --

13 THE COURT: I sustained the objection.

14 THE WITNESS: Oh, okay.

15 MR. LOPEZ: Pass the witness, Your Honor.

16 THE COURT: All right.

17 MR. CONDO: May I proceed?

18 THE COURT: Yes.

19 CROSS-EXAMINATION

20 BY MR. CONDO:

21 Q. Mr. Tessmer, when you left Bard for the first time in 2005,  
22 June of 2005, did you go to another company?

23 A. Yes, I did.

24 Q. And did your new job have anything to do with IVC filters?

25 A. No, it did not.

1 Q. And you've already told the ladies and gentlemen of the  
2 jury that your new job has nothing to do with IVC filters;  
3 correct?

4 A. That is correct.

5 Q. So you haven't had any firsthand or direct involvement with  
6 IVC filters since you left in 2005?

7 A. That is correct.

8 Q. During the time that you were at Bard in the early 2000s,  
9 what was the main thing that you were working on?

10 A. I was working on the jugular delivery system.

11 Q. And what is the jugular delivery system?

12 A. So it's basically the delivery system that would deploy the  
13 filter. So we had a femoral delivery system that would use a  
14 femoral approach, which is in the groin area, and you approach  
15 up the femoral artery. And they wanted one for a jugular  
16 approach, to come in your neck from your jugular vein to deploy  
17 it this way.

18 And so my job was to design the actual -- the delivery  
19 device.

20 Q. Was it your job to figure out how to get a filter that  
21 someone else designed to deploy properly in the patient and  
22 then to be retrieved in the patient?

23 A. It was, yeah, to deploy properly in a patient, correct.

24 Q. And it was someone else's responsibility, not yours, to  
25 design the filter that you were working on the delivery system

1 for; correct?

2 A. That is correct.

3 Q. Now, I think you told the ladies and gentlemen of the jury  
4 that from time to time you got called in to do projects for the  
5 Recovery filter. Correct?

6 A. That is correct.

7 Q. And was that the migration testing that you discussed with  
8 Mr. Lopez?

9 A. It was.

10 Q. And did these projects from time to time take you away from  
11 your primary responsibility, which was the delivery system, the  
12 jugular delivery system?

13 A. Yes.

14 Q. And who was the person who from time to time would call you  
15 in and ask you to take on these new assignments?

16 A. It would be my boss, Rob Carr.

17 Q. And at the time, were you a relatively junior engineer in  
18 the research and development group?

19 A. Yes.

20 Q. And when the tests were run on the Recovery filter, you  
21 were the one who was actually reporting the results. Do I  
22 understand that correctly?

23 A. That is correct.

24 Q. But did you run the tests yourself?

25 A. I did not.

1 Q. You drafted the test protocols for some of the tests; is  
2 that correct?

3 A. That's correct.

4 Q. Were you the one who had to approve the test protocols?

5 A. I would approve, and others would approve as well.

6 Q. You didn't have the ability to simply decide that a test  
7 would be run according to a specific protocol all by yourself,  
8 did you?

9 A. That is correct.

10 Q. And who told you what tests to run?

11 A. My boss.

12 Q. Were you given any choice in deciding which tests to run?

13 A. No.

14 Q. Did you have any decision-making responsibility after you  
15 reported the test results to Mr. Carr and others as to what  
16 would be done with those test results?

17 A. No, I did not.

18 Q. Were all of the migration tests that Mr. Lopez showed you  
19 tests that related to the Recovery filter?

20 A. Yes, they were.

21 Q. Did he show you any tests related to the G2X filter?

22 A. Not that I saw.

23 Q. Did he show you any tests related to the Eclipse filter?

24 A. Not that I saw.

25 Q. Were all the Recovery migration tests that were shown to

1 you by Mr. Lopez cranial migration tests?

2 A. Were they cranial migration tests?

3 Q. Yes.

4 A. Yes.

5 Q. Were any of them caudal migration tests?

6 A. No.

7 Q. Your involvement with the development of the G2 was even  
8 more limited than your involvement with the Recovery filter;  
9 correct?

10 A. That is correct.

11 Q. Because you were, as I understand it, charged with  
12 developing the deployment system for the G2?

13 A. Correct.

14 Q. A new filter that you didn't have any design input on; is  
15 that correct?

16 A. That is correct.

17 Q. Were you involved in any fashion with the development of  
18 the G2X filter?

19 A. No, I wasn't.

20 Q. Were you involved on any of the regulatory filings that  
21 were made to the FDA related to the G2X filter?

22 A. No.

23 Q. In fact, was the G2X filter cleared by the FDA and  
24 introduced into the market after you left Bard, to your  
25 understanding?

1 A. To my understanding, yes.

2 Q. Were you involved with the Eclipse filter in any fashion?

3 A. No.

4 Q. Did you perform any testing on the Eclipse filter?

5 A. No, I did not.

6 Q. Were you involved in any regulatory filings made to the FDA  
7 related to the Eclipse filter?

8 A. No, I wasn't.

9 Q. We've heard testimony in this courtroom that the Eclipse  
10 filter was electropolished. Did you have any involvement in  
11 developing the electropolishing process for the Eclipse filter?

12 A. No.

13 Q. You've made reference to Mr. Carr, and I think we saw a  
14 document that identified him as the team leader?

15 A. That is correct.

16 Q. You also mentioned Mr. Chanduszek, but we don't have a  
17 title for him. To your understanding, what was his involvement  
18 as you were able to discern in connection with the Recovery  
19 filter?

20 A. He was an engineer and involved in designing the filter.

21 MR. CONDO: Thank you. I have no further questions.

22 THE COURT: Redirect.

23 REDIRECT EXAMINATION

24 BY MR. LOPEZ:

25 Q. Mr. Chanduszek [sic], I didn't ask you questions about the

1 G2X and the Eclipse, and had I, you wouldn't have known  
2 anything about that; right?

3 A. Correct.

4 Q. And Mr. Condo just brought something up. There was no  
5 caudal testing of the G2 or the Recovery; true? Bench testing?

6 A. Not that I'm aware.

7 Q. Did they tell you that there had been some caudal migration  
8 reports in the Asch study and in the field with the Recovery  
9 filter before you did your test?

10 A. I was unaware.

11 Q. So the G2 device was launched into the U.S. marketplace  
12 without Bard having even done a bench test to see whether or  
13 not its new design would cause it to actually move downwards;  
14 true?

15 A. I don't know what testing was done, so...

16 Q. And you also mentioned electropolishing. Is that an  
17 engineering concept, design that you were familiar with when  
18 you were working at Bard?

19 A. Somewhat.

20 Q. And what is electropolishing?

21 A. It's just basically where they take the -- they smooth out  
22 the surface of the Nitinol, and I think it gets like an oxide  
23 coating on it.

24 Q. And what's the purpose of electropolishing?

25 A. I think it enhances the strength of the filter, but I would



1 defer to Andre for that.

2 Q. And that was never done to the G2 filter was it,  
3 electropolishing?

4 A. I don't know.

5 Q. Was Bard actually electropolishing other medical devices  
6 that they were manufacturing and selling while you were at  
7 Bard?

8 A. I'm unaware.

9 Q. And no one asked you to look into what electropolishing  
10 might do to increase the fracture resistance of the Recovery  
11 filter or the G2 filter; true?

12 A. True. I was -- I worked on the delivery system, not the  
13 filter.

14 Q. Now, at any time while you were there -- I know you were  
15 only there for a short time working on filters. Did anyone,  
16 Mr. Carr, Mr. Chanduszko, anyone at Bard ever say, "We need you  
17 to run some tests on our Simon Nitinol filter because we're  
18 having some field complaints about migration, fracture,  
19 perforation, tilt," anything like that?

20 MR. CONDO: Beyond the scope of cross.

21 THE COURT: Sustained.

22 MR. LOPEZ: Nothing further, Your Honor. Thank you.

23 THE COURT: All right. Thank you.

24 You can step down.

25 THE WITNESS: Thank you.

1 (Witness excused.)

2 MR. O'CONNOR: Your Honor, at this time we're going to  
3 call Mr. Tim Hug.

4 THE COURTROOM DEPUTY: Sir, if you'll please come  
5 forward and raise your right hand.

6 (The witness was sworn.)

7 THE COURTROOM DEPUTY: Please state and spell your  
8 name for the record.

9 THE WITNESS: Sure. Timothy Hug. It's T-I-M-O-T-H-Y,  
10 Hug, H-U-G.

11 THE COURTROOM DEPUTY: Thank you. Please come have a  
12 seat.

13 TIMOTHY HUG,  
14 called as a witness herein by the plaintiffs, having been first  
15 duly sworn or affirmed, was examined and testified as follows:

16 DIRECT EXAMINATION

17 BY MR. O'CONNOR:

18 Q. Mr. Hug, my name is Mark O'Connor. How are you? We  
19 haven't met before, have we?

20 A. We have not.

21 Q. Well, nice to meet you.

22 A. Nice to meet you.

23 Q. Do you live here in Arizona now?

24 A. I do.

25 Q. How long have you been here?

1 A. I moved on July 5th of 2017, so just over a year.

2 Q. Was that from Wisconsin?

3 A. It sure was.

4 Q. Big change?

5 A. Big change. Big change.

6 Q. Well, thanks for coming down today.

7 You work for Bard; is that correct?

8 A. That is correct, sir.

9 Q. In Tempe?

10 A. That is correct, sir.

11 Q. And as I understand, you are the vice president of sales?

12 A. I am, sir.

13 Q. And how long have you held that position?

14 A. Since approximately January of 2017. So just over a year  
15 and a half.

16 Q. You are new --

17 A. Yes, sir.

18 Q. -- to the area.

19 And before that, I think you were regional manager?

20 A. I had a variety of different roles, but yes, including a  
21 regional manager.

22 Q. So, quickly, when did you start at Bard?

23 A. Sure. In 2007 I started out as a representative. I  
24 carried the bag, if you will. I was a territory manager. And  
25 then I became a district manager approximately two years later,

1 so I was kind of a manager of representatives. And then after  
2 that, I was a regional manager, so sort of like a manager of  
3 managers.

4 And then at that point I became what's called a  
5 Lutonix business director. I won't go into the details, but  
6 basically it's sort of a launch manager, for a couple years.  
7 And then I became director of sales for the peripheral sales  
8 team, so the team that deals with peripheral arterial disease,  
9 so blockages in the leg. And then in January of 2017 I became  
10 vice president of sales, sir.

11 Q. What was your position in 2011?

12 A. I'd have to check, but I believe I was district manager at  
13 that time, sir.

14 Q. At that time you were also supervising a Bard employee, a  
15 sales representative by the name of Matt Fermanich?

16 A. That is correct, sir.

17 Q. And he reported to you?

18 A. He was one of the representatives, yes, sir.

19 Q. So is it fair to say, sir, that the entire time you've been  
20 at Bard, you've been involved in sales?

21 A. Yes, sir.

22 Q. And you're responsible in the time you've been at Bard for,  
23 among other things, the promotion of Bard devices; correct?

24 A. Yes, sir.

25 Q. And when you talk about Bard Peripheral Vascular here in

1 Tempe, when we think of IVC filters, which we're here to talk  
2 about, that's where that business is handled; correct?

3 A. That is correct. Our headquarters for that is in Tempe,  
4 Arizona, sir.

5 Q. And in 2011, so were you the regional sales manager at that  
6 time?

7 A. Yeah. We called it a district sales manager, but yeah. If  
8 I could, sir.

9 Q. Yeah, I still -- I've seen that -- but I'll leave it at  
10 district sales manager.

11 And at that time, what was your area?

12 A. Sure. My recollection is is that I covered the great state  
13 of Wisconsin and then a variety of other sort of central  
14 states. So, for example, Illinois, parts of Michigan, and I  
15 believe Minnesota at the time.

16 Q. And you oversaw sales representatives?

17 A. Yes, sir.

18 Q. And territory managers?

19 A. Yes, sir.

20 Q. And what you oversaw was a sales force responsible for  
21 promoting and selling Bard products; correct?

22 A. That's correct, sir.

23 Q. And even now, I think I saw in your deposition where you're  
24 responsible for the commercialization of Bard devices and  
25 products?

1 A. Yes, sir.

2 Q. And in 2011 and even now, is it fair to say that one of  
3 your responsibilities is to monitor the sales force?

4 A. That is correct, sir.

5 Q. And when you were doing your work as a district manager,  
6 you were responsible to coach, educate, and help your sales  
7 force with the development and promotion of Bard products; is  
8 that fair?

9 A. That is a fair characterization, sir.

10 Q. And what that means is that in sales, in Bard, what's  
11 important is relationships with the medical community; fair?

12 A. Fair, sir, yes.

13 Q. And what you would do was you would help your sales  
14 representatives develop those relationships, which would  
15 hopefully result in the sale of Bard devices and products?

16 A. Yeah, that would be one aspect of my job, sir, yes.

17 Q. And I understand. I think you probably were working on  
18 educating and training people; true?

19 A. Absolutely true, sir, yes.

20 Q. And working with people and helping them make sales, which  
21 in turn would help Bard be competitive?

22 A. Yes, sir. I believe that's a fair characterization, sir.

23 Q. As a matter of fact, sales works a little bit differently  
24 than other parts of the company because they -- people in sales  
25 are paid in a way that provides an incentive; correct?

1 Commission?

2 MR. CONDO: I would object, Your Honor. I think this  
3 is covered by your Hudnall ruling.

4 THE COURT: I don't know what you're referring to.

5 Come up here, if you would.

6 MR. CONDO: Is there a bean left?

7 THE COURT: One.

8 Go ahead and stand up, if you'd like.

9 (At sidebar on the record.)

10 THE COURT: There's only going to be three on Monday.

11 Go ahead.

12 MR. CONDO: I think, Your Honor, when you went through  
13 on the 18th and explained your rationale for drawing the line  
14 between the duty -- the failure to warn claim and the design  
15 defect claim and the physician -- where physician expectations  
16 fell in that continuum, I think you used several times the  
17 phrase "marketing techniques." Things that went to how the  
18 product was marketed.

19 And you addressed in Janet Hudnall's deposition, I  
20 think, as Your Honor explained it --

21 THE COURT: I remember.

22 MR. CONDO: -- the --

23 THE COURT: I just didn't know what you were referring  
24 to.

25 MR. CONDO: And I didn't know how else to refer to it.

1 And I think once you start talking about incentive compensation  
2 and you start talking about sales competitions and things like  
3 that, we have moved into the area of marketing techniques that  
4 have nothing to do with the design defect claim that remains.

5 MR. O'CONNOR: Well, I disagree. I mean, first of  
6 all, they've raised this product identification issue. And one  
7 of the issues is going to be what happened in his district in  
8 Wisconsin.

9 Our position is, and we have evidence, that even  
10 though the Eclipse was on the market and the failed Eclipse was  
11 coming right around the corner, that there were still G2Xs and  
12 G2s in the hospital where Mrs. Hyde received her filter.

13 THE COURT: Well, but he didn't object to that. He  
14 objected to your starting to ask about being paid by  
15 commissions. Where are you going with that?

16 MR. O'CONNOR: Because I want to go into documents  
17 that showed how they were incentivizing them to get the  
18 Meridian out there, and eventually the Meridian ran out and  
19 they were back to the G2.

20 And, you know, I mean, we're up here and now I'm  
21 giving away my whole strategy of this cross-examination, but  
22 that's where I'm going to go.

23 And, Your Honor, I mean, when you get to Wisconsin  
24 punitive damages, how they handle the product, how they handle  
25 the information, what the employees know, if they're involved



1 in the concealment, those are all relevant issues.

2 THE COURT: Well, the whole failure to warn case can  
3 be relevant under that thinking. Everything they did in a  
4 failure to warn could arguably be relevant.

5 MR. O'CONNOR: Well, I'm not going into everything the  
6 failure to warn --

7 THE COURT: Well, it sounds like you want to get into  
8 sales techniques, you want to get into sales compensation, and  
9 I'm having trouble understanding what that has to do with the  
10 design defect.

11 MR. O'CONNOR: Well, it's going to go to the product  
12 identification.

13 THE COURT: What does commissions have to do with  
14 product identification?

15 MR. O'CONNOR: Because, Your Honor, at the same time  
16 they're going to claim -- I think we're going to show this jury  
17 that even though they want to claim that this was the Eclipse  
18 and maybe the Eclipse was there because they believed it was a  
19 better product, she got a G2. And she got a G2 --

20 THE COURT: What does compensation have to do with  
21 that?

22 MR. O'CONNOR: Because there's going to be evidence in  
23 the same time period that they were talking about a Meridian  
24 promotional project where they were going to win monetary  
25 prizes.

1 THE COURT: What has that got to do with whether this  
2 was a G2X?

3 MR. O'CONNOR: It goes to show how confused this  
4 company was about what device should be there and how they  
5 ignored -- and it goes to their disregard of patient rights.  
6 Because they were so focused on trying to get a different  
7 device out, they neglected a hospital that still had these G2s  
8 and G2Xs.

9 THE COURT: I don't see any connection between being  
10 paid by commission and whether it was a G2X at this hospital.  
11 That's what I'm struggling with.

12 MR. LOPEZ: Well, I -- you don't want two of us to  
13 talk.

14 THE COURT: You can talk. Go ahead.

15 MR. LOPEZ: I think we made this point before, but the  
16 IFU is obviously in full bloom. When they market these things,  
17 they say they're restricted to just the IFU and to stay within  
18 the IFU.

19 Well, if they're marketing this thing based on  
20 information that is not in the IFU, that means they're  
21 marketing it in a manner in which doctors are -- you know, have  
22 a certain idea about the performance of this thing when, in  
23 fact, marketing -- the guys that are in sales are not meeting  
24 the reasonable expectations of doctors because what's in the  
25 IFU does not describe what the true performance is of this

1 device.

2 THE COURT: What has that got to do with commission  
3 compensation?

4 MR. LOPEZ: Because -- Your Honor, because it has to  
5 do with the fact that they're being incentivized to not focus  
6 on anything else but to sell this device against other devices.  
7 And to -- and to maintain that message that we've -- we're the  
8 strongest, the most durable, the best device on the market.

9 I mean, this is -- if labeling is going to come into  
10 this as something that fixes the design, then we have -- I  
11 think we have the right to tear down the labeling. And the  
12 labeling is not just what's buried in an IFU; it has to do with  
13 the messaging that the company gives to the doctors. The  
14 doctors don't even read it.

15 THE COURT: Well, hold on, Mr. Lopez. I know you  
16 could go on for another five minutes on this, genuinely. I  
17 mean, I'm not being critical, but I don't want to do that while  
18 the jury's waiting.

19 The line I've tried to draw is you can bring out facts  
20 that weren't disclosed, information that wasn't conveyed to  
21 doctors, because that goes directly to the question of whether  
22 there was a basis for them to deal with it in a reasonably safe  
23 manner.

24 It seems to me it's a far cry from that to get into  
25 incentives of salespeople. I mean, you can bring -- if you

1 think there are facts they didn't disclose, that's fair game.

2 But I don't understand how compensation incentives --

3 MR. LOPEZ: Well, let me take one more shot at it.

4 THE COURT: Okay.

5 MR. LOPEZ: Because I think what we have -- when we're  
6 talking about the design and all these issues that deal with  
7 liability and you have a punitive damage claim, it goes to the  
8 conduct and the attitude of the company in view of this device  
9 having design problems.

10 THE COURT: Well, here's the problem I have with that,  
11 so you can address it.

12 Let's say you convince this jury that they were bad  
13 marketers, that they lied when they talked to doctors.

14 MR. LOPEZ: Uh-huh.

15 THE COURT: That's not punitive conduct for a  
16 defective design. I mean, the only punitive damages that can  
17 be awarded in this case are for defectively designing a  
18 product.

19 MR. LOPEZ: Okay.

20 THE COURT: There isn't a fraudulent marketing claim  
21 that could be a basis for punitive damages, and yet it sounds  
22 to me like you want to say this company was behaving badly in  
23 how it was misrepresenting or omitting information in its  
24 marketing for purposes of punitive damages. That seems to me  
25 to be a far cry from designing a defective product to justify

1 punitive damages.

2 MR. LOPEZ: Well, I mean, you know, the way we all --  
3 we read this, especially the negligence part of this -- I know  
4 Your Honor has read it differently than we have about letting  
5 in IFUs, SIRs, FDA, and all that stuff. I mean, it's like,  
6 well, that seems to be going to an extreme on whether or not  
7 the company is looking at a design of its product, realizing  
8 it's failing. It's not performing. They're not testing it.

9 I have no idea what an IFU and the SIR guidelines and  
10 FDA have to do with that, but I'm living with that. But if I  
11 have --

12 THE COURT: Well, I'm really comfortable on that.

13 MR. LOPEZ: I know you are.

14 THE COURT: Because of what the restatement says and  
15 what your own expert said. Dr. McMeeking said: You got to  
16 tell the user of the risks so that they can take those into  
17 account and deal with it in a safe manner.

18 MR. LOPEZ: Let me take one more shot.

19 THE COURT: Okay.

20 MR. LOPEZ: The conduct is, in this case, in the  
21 negligent design part of the case, the conduct that's --

22 THE COURT: It's negligent design. I agree with that.

23 MR. LOPEZ: As it pertains to the conduct of the  
24 company. And if there are things relating to the design of  
25 this product that have deprived our client of her rights to

1 know exactly why this thing is being put in her, and that is  
2 maybe because the marketing department and sales department are  
3 aggressively marketing this product without knowing anything  
4 that she's supposed to know --

5 MR. O'CONNOR: And her doctor.

6 MR. LOPEZ: -- and a reasonable doctor's supposed to  
7 know, how is a reasonable -- we've had reasonable doctors now  
8 testify already twice that a reasonable -- in fact, we've had  
9 some of their corporate people say that reasonable doctors'  
10 expectations would be that the company would be forthright and  
11 transparent and tell us about everything that they know about  
12 this product so we can make an informed decision about whether  
13 or not we're going to use the device.

14 If that is being masked by the conduct of the  
15 company's marketing practices, I mean, that is relevant on --  
16 you know, her -- the violation -- I don't have the statute in  
17 front of me. I probably couldn't read it right now if it was  
18 there, but this goes to punitive damages because it's immersed  
19 in the conduct that has caused this device to be negligently  
20 designed and not fixed.

21 I mean, I don't know how to pull it out of there. I  
22 don't. Because the conduct's always going to be involved in  
23 why -- in the why part of the case, Judge. I mean, the why  
24 part of the case, you have to look at why. Why did this  
25 happen?

1           And if it happened because the defendants were more  
2           focused on bonusing their sales reps and marketing this product  
3           and not fixing it, we have a right to make that argument, I  
4           think, to the jury.

5           THE COURT: Well, I hear what you're saying. I mean,  
6           I still am of a view that the line that should be drawn is  
7           based on the statute. The question is was there a reasonable  
8           alternative design that wasn't used, and was the failure to use  
9           that reasonable alternative one that made the product not  
10          reasonably safe. That's ultimately what the jury's going to  
11          have to decide in this case.

12          And I've concluded that whether or not the product is  
13          reasonably safe when used depends in part upon what the doctor  
14          was told about how to use it. And if he wasn't told of risks,  
15          then it might not be reasonably safe to use it. And that's why  
16          I think the failure to disclose risks is very relevant to that.

17          MR. LOPEZ: But if that was motivated by profit over  
18          safety -- I mean, we have -- if this case is about that -- them  
19          having failed there because they put their profits and their  
20          marketing share over safety, we have a right to tell the jury  
21          that under -- you know, under the punitive -- at least the  
22          punitive damage part of this case and maybe to explain why  
23          it -- you know, that that didn't happen.

24          It didn't happen because this was a new iteration that  
25          was so wonderful because we're making now our fifth case and

1 we're doing what any prudent medical device manufacturer is,  
2 and that is always trying to improve our product. No.

3 They're doing it because they're protecting the market  
4 share. And we have evidence of that in this case. You know,  
5 we have evidence --

6 THE COURT: Hold on just a minute. This would be  
7 easier if it wasn't Friday afternoon.

8 Mr. Condo, if it is relevant to the design defect  
9 claim for the jury to know what was told to doctors and  
10 patients and what wasn't told to doctors and patients -- which  
11 you've argued that it is relevant. That's why you wanted to  
12 get in the IFU -- why is it not also relevant as part of  
13 plaintiffs' case for them to say part of the proof that the  
14 whole truth wasn't told is found in the financial motivation of  
15 the company and of the people who were selling it?

16 That's part of the picture that proves that the whole  
17 truth wasn't told, and therefore, that the product was not  
18 reasonably safe because people didn't know everything they  
19 needed to about it.

20 I think that's --

21 MR. LOPEZ: It is.

22 THE COURT: -- your point.

23 MR. CONDO: Well, and I may call on Mr. Rogers here --

24 THE COURT: That's all right.

25 MR. CONDO: -- to assist me.



1 But I think, Your Honor, if we understand the way you  
2 have drawn the line and what the jury will be instructed, the  
3 issue of design defect is a different issue than whether or not  
4 they were compensated appropriately or inappropriately.

5 The issue, as we understand it, is is the design  
6 defective. And there's been no testimony, Your Honor, about  
7 any of the failure to warn issues. We've kept that out so far.  
8 We've stayed away from that.

9 And I don't see -- and again, maybe it would be easier  
10 if it weren't Friday afternoon, but I don't see how if what  
11 you're saying is the motive to design the product defectively  
12 was driven by sales, they can --

13 THE COURT: No, I'm not saying that.

14 MR. CONDO: They can argue that.

15 THE COURT: I'm not saying it. That's not my point.  
16 I don't think that's his point.

17 MR. LOPEZ: No.

18 THE COURT: Let me try it again.

19 MR. CONDO: I'm sorry. Then I misunderstood.

20 THE COURT: The thing that first convinced me that the  
21 jury should hear information about what the doctors received  
22 was your argument that the fact that the doctors had the IFU  
23 helped make this a reasonably safe product, which is the second  
24 part of the test. Because doctors understood the risks. They  
25 understood how to use it. They could do an analysis and use it

1 in a safe manner.

2 And I thought, yeah, you're right. What the doctors  
3 knew has a lot to do with whether the product was safe.

4 So we started down the road of saying, okay, what is  
5 communicated about the product bears on the question of whether  
6 it's safe. Well, that necessarily has to include what wasn't  
7 communicated about the product. Because if they can show that  
8 the risks were much greater than were stated in the IFU, that  
9 helps show the doctors couldn't use it in a reasonably safe  
10 manner, and the jury can therefore say it wasn't reasonably  
11 safe.

12 That's why I've opened the door to what the doctors  
13 were told. I understand Mr. Lopez and Mr. O'Connor to be  
14 arguing that in order to prove what the doctors did and didn't  
15 know, it's important for the jury to understand the financial  
16 incentives of who was speaking to. And the incentive was such  
17 so as not to be forthcoming.

18 MR. CONDO: And the question for the jury is not why  
19 they weren't told that. The question is what were they told.  
20 That will be the ultimate decision that the jury has to answer.  
21 That is why this is not relevant. The question is what were  
22 they told. That's the ultimate question the jury is going to  
23 have to decide.

24 THE COURT: Did you want to say something?

25 MR. ROGERS: No. Mr. Condo summed it up. I think if

1 you move into a situation where you have the potential for them  
2 awarding punitives based on the motivation as to what the  
3 doctors were told, you are then awarding punitives based on a  
4 claim that is not in the case.

5 We agree completely that plaintiffs can introduce  
6 evidence of what was not told if the lack of information goes  
7 to how the doctors would understand how to use the product.  
8 And that is completely relevant. But motivation for what  
9 they're not told, you are then allowing a punitive award based  
10 on a claim that's not in the case.

11 THE COURT: I know you have much to say.

12 MR. LOPEZ: I do.

13 THE COURT: Hold on just a moment.

14 MR. LOPEZ: Okay.

15 THE COURT: How long do you have with this witness?

16 MR. O'CONNOR: Well, I mean, it depends.

17 THE COURT: If you don't go into the sales commission  
18 stuff, how long do you have with this witness?

19 MR. O'CONNOR: Well, I kind of need these sales for a  
20 little background of where I want to go, but I'll try to work  
21 it --

22 THE COURT: Well, no. I'm trying to figure out if we  
23 should keep the jury waiting while we continue to wrestle with  
24 this. Because I think this is -- the reason I'm taking so much  
25 time on the sidebar is because this is an important issue in

1 the case. This is going to determine where you get to go on  
2 some of your evidence, and he's on the stand and I want to make  
3 sure --

4 MR. O'CONNOR: I have a lot with him, and depending on  
5 how you rule is going to change things. Because what I have  
6 set up and the year that's important to me with this witness is  
7 the year 2011. And what I intend to elicit from him is  
8 information about sales, products that were being pushed, the  
9 incentives that were given to the salespeople to push these  
10 products, and how other devices and how other hospitals were  
11 overlooked.

12 THE COURT: Well, it seems to me you could, so that I  
13 have time to think about this when it's not 4:00 o'clock on a  
14 Friday afternoon, you could cover 2011, what products were  
15 being sold, what was in various hospitals, et cetera. And then  
16 if I allow it, you could come back on Monday and talk about the  
17 incentives that were behind it all.

18 And if we don't do that, I've got to make a call now.

19 MR. O'CONNOR: The documents that I'm using are sales  
20 documents which have points in time. I think they're  
21 admissible as business documents. I think they're admissible  
22 for a lot of reasons, but they have sales information in them,  
23 sales contests and that.

24 And I'm using those to set up --

25 THE COURT: Okay. So you're saying I do need to make

1 the decision now.

2 MR. LOPEZ: Well, maybe not -- well --

3 THE COURT: Well, I will --

4 MR. O'CONNOR: Let me try to work it --

5 THE COURT: This may influence you. I tell you, I'm  
6 leaning away from allowing this right now, because I think it  
7 opens the door to a full-blown failure to warn case, and that's  
8 not what this is. And I think it very much opens the door to  
9 the jury awarding punitive damages on a failure to warn and bad  
10 intent behind a failure to warn. That's not in this case.

11 I understand your argument, and I think it's relevant,  
12 but we've got to draw the line somewhere on that continuum.  
13 And I'm inclined to draw it at the point of what were they  
14 told, from both of your perspectives, but rather get in -- than  
15 get into motives and things like that and strategy. That's  
16 where I'm inclined to draw the line now.

17 MR. O'CONNOR: Your Honor, I'm being forced to give up  
18 some work product here, but one of the important --

19 THE COURT: Well, I can rule now. I'm just telling  
20 you --

21 MR. O'CONNOR: But I want you to understand the line  
22 of questioning where I think --

23 THE COURT: Okay.

24 MR. O'CONNOR: -- I think this is relevant. That what  
25 was important to them were relationships with doctors and how

1 doctors relied on sales to give them accurate information and  
2 the sales department relied on Bard. That's going to be an  
3 important feature.

4 THE COURT: That's fair. I think that's fair. That  
5 doesn't get into compensation and incentives.

6 MR. LOPEZ: I think you can do that without --

7 MR. O'CONNOR: And, you know, we're going to be up  
8 here again because I have emails on this product identification  
9 issue that start with Mr. Hug, then they go to Mr. Fermanich.  
10 And we've already got wind from these guys they're going to  
11 make some objection on it. I don't know what it's going to be.

12 THE COURT: What's going to be the basis for the  
13 objection?

14 MR. CONDO: Get more beans.

15 THE COURT: Hold on. Look, we're almost at 4:00. We  
16 can't keep doing this.

17 MR. CONDO: I'm not sure what he's talking about. If  
18 it's an email from Mr. Hug to Mr. Fermanich and it doesn't  
19 include the kinds of marketing techniques that we're objecting  
20 to, I don't know that --

21 THE COURT: Well, we can do what we've done before,  
22 which is we can put it in and not show the marketing technique  
23 stuff to the jury, and if I rule against you on that, we can  
24 redact it later.

25 MR. O'CONNOR: No marketing techniques. It's an email

1 that goes from Hug to Fermanich, from a hospital employee to  
2 Hug, Hug -- she identifies the problem. Two emails. He says  
3 Matt Fermanich is the person you got to get. The email goes to  
4 Fermanich and this hospital person.

5 MR. CONDO: Well, then there's hearsay issues with  
6 that.

7 THE COURT: Well, I'll have to deal with hearsay  
8 issues.

9 MR. O'CONNOR: I don't think there is a hearsay issue.

10 THE COURT: Well, you can explain why when we get  
11 there.

12 MR. O'CONNOR: Well, we're going to be back up so --  
13 if I'm going to switch, we're going to be back up. I'm just  
14 telling you, Judge, we are going to be back up here.

15 MR. LOPEZ: It's this whole product ID thing. Wait  
16 till you see the evidence, what was going on.

17 MR. O'CONNOR: Let me go where I'm going to go with  
18 him. We'll see.

19 THE COURT: All right. Well, I do not want to have  
20 another sidebar on this jury.

21 MR. O'CONNOR: I don't either.

22 THE COURT: Let's go for the 35 minutes without  
23 raising those issues if we can. Without getting us back up  
24 here if you can.

25 MR. O'CONNOR: If I'm not going to be able to do this,

1 I got to get right into that issue.

2 THE COURT: You what?

3 MR. O'CONNOR: If I'm not going to go here, I have to  
4 get right into that issue.

5 THE COURT: Well, you've heard my thinking. Do the  
6 best you can.

7 (End of discussion at sidebar.)

8 THE COURT: Thanks, ladies and gentlemen. Sorry, that  
9 broke a record. We'll try not to break it again.

10 Go ahead, Mr. O'Connor.

11 BY MR. O'CONNOR:

12 Q. Mr. Hug, what was important for you and your sales force, I  
13 think you told us, was to develop relationships with the  
14 medical community, including doctors; correct?

15 A. That is correct, sir.

16 Q. Good relationships are based on trust; you would agree with  
17 that?

18 A. Yes, the best ones are. Yes.

19 Q. And certainly you wanted your sales reps to develop such a  
20 relationship with doctors in the medical community so that the  
21 medical community, the customers, could rely on your sales reps  
22 for truthful and accurate information about Bard devices;  
23 correct?

24 A. Can you ask me that question again?

25 Q. Sure.



1           What was important about the relationship and what you  
2 encouraged your sales reps to do would be develop relationships  
3 that were built on trust. Fair?

4     A. That is fair, sir.

5     Q. And you wanted your sales force to set up a relationship  
6 whereby a doctor knew he or she could rely on a member of the  
7 sales force for truthful and accurate information about Bard  
8 devices; fair?

9     A. Yes. That's fair. Our -- yes.

10    Q. And you and your sales force in turn relied on the company  
11 to supply you with any information you needed to know, for  
12 example, about IVC filters?

13    A. Yes. The company trained us, and -- accordingly, initially  
14 and throughout my tenure, yes, sir.

15    Q. And that would include strengths and weaknesses of the  
16 devices; true?

17    A. That is true. The data that's in our IFU, for example,  
18 yes, sir.

19    Q. All right. Thank you.

20           Now, going back in time a little bit while you were in  
21 Wisconsin, in Milwaukee. And Matt Fermanich was on your sales  
22 force; correct?

23    A. He was, sir.

24    Q. Is he still with the sales force of Bard?

25    A. He is.

1 Q. All right. And Matt Fermanich, is he still a sales rep,  
2 representative?

3 A. He is not. He was promoted to a manager role, sir.

4 Q. Well, tell him I said congratulations.

5 A. I will, sir.

6 Q. I've met Matt.

7 A. Okay.

8 Q. But one of the hospitals in the Milwaukee area that Matt  
9 was responsible, and ultimately you were responsible for, was  
10 Wheaton Franciscan Health Systems; correct?

11 A. That is correct, sir.

12 Q. And that's in the Milwaukee area?

13 A. It is.

14 Q. And there's one in Franklin; right?

15 A. Yes. That is one of the hospitals that is part of the  
16 Wheaton Franciscan Hospital System, yes, sir.

17 Q. And for Matt to act within the course and scope of his  
18 employment as a Bard sales representative, you assisted him in  
19 having communications and promoting products and devices there;  
20 correct?

21 A. Yes.

22 Q. And if a customer had questions from any hospital or any  
23 healthcare provider about a device, he or she could contact  
24 you, Tim Hug?

25 A. They could.

1 Q. And oftentimes you might refer them to the person who was  
2 responsible for the hospital; correct?

3 A. Yeah. Normally they would contact the territory rep, so  
4 Matt Fermanich. Sorry, I have to -- it's Fermanich. But,  
5 yeah, I'm flowing with you here.

6 Q. Is it Fermanich?

7 A. It is. But you're good, though.

8 And then -- and then they would normally contact him.  
9 But if something needed to get escalated or Matt had a  
10 question, right, they would either contact me or Matt would  
11 contact me, sir.

12 Q. Part of Matt's --

13 A. You're great. Don't worry about Matt, yeah.

14 Q. I want to make sure I get it right. Fermanich?

15 A. Fermanich.

16 Q. Fermanich?

17 A. Yeah.

18 Q. Part of his job, the course and scope of his job was to  
19 respond to concerns or questions of customers of his in the  
20 Milwaukee area; fair?

21 A. That is fair, sir.

22 Q. And if he had any questions, he could come to you; correct?

23 A. That is correct, sir.

24 Q. And there were times when a customer may contact you and  
25 you, in turn, would direct that customer to somebody like Matt

1 to respond to the question or the concern?

2 A. Sure. For example, specifically in Milwaukee, that used to  
3 be my old territory so I knew a lot of those customers. So  
4 yes, sir.

5 Q. And that probably gave you an advantage in training your  
6 sales force in that area because you could help people like  
7 Matt develop relationships and promote devices?

8 A. Some would differ with the term "advantage," but perhaps it  
9 did -- it did help Matt out, I'm sure, so sure.

10 Q. Now, you were there at Bard when the G2 and G2X were being  
11 promoted; correct? The filters?

12 A. I believe that's accurate. I think in 2007 when I started,  
13 the G2 was part of the filter actually there, yes, sir.

14 Q. And the IVC devices were within your responsibility in  
15 terms of promotions, sales in that area, the region of -- that  
16 included Milwaukee, Wisconsin?

17 A. Yes, sir. At that time, yes, sir.

18 Q. Right. And I'm just focused right now 2010/2011.

19 And at some point in time you had the G2, the G2X, and  
20 then do you recall when the Eclipse filter came on the market?

21 A. I can't recall specifically, but I do know it was after.

22 Q. Let me show you what's been marked as Exhibit 4843.

23 Do you recognize this document? It's a Bard document.  
24 You see the Bard letterhead?

25 A. I see the letterhead. This looks like it was from Bill

1 Little, who was our -- I believe our VP of marketing, to the  
2 filter marketing team, so it doesn't look like I would have  
3 seen this document, sir.

4 Q. Well, it appears to be a Bard document on business -- on  
5 Bard's business letterhead; correct?

6 A. It does, sir. I just would have no -- I wouldn't have seen  
7 this, more than likely, sir.

8 Q. And you were aware of the Eclipse anchor project; correct?

9 A. I was --

10 Q. Meridian?

11 A. Yeah. It just kind of depends when. Sure. At training or  
12 at the start of the launch of it, absolutely, sir.

13 MR. O'CONNOR: Your Honor, at this time I would move  
14 to admit 4843.

15 MR. CONDO: No foundation.

16 THE COURT: Sustained.

17 MR. O'CONNOR: I'm asking for it to come in under the  
18 business exception, and to establish when the anchor project  
19 started. Independently --

20 THE COURT: You haven't laid -- you haven't laid  
21 foundation under 803(6).

22 BY MR. O'CONNOR:

23 Q. Do you recall discussions about the Eclipse anchor project  
24 back in 2010?

25 A. I'm sorry, I don't recall that, sir.

1 Q. All right. Let's show you Exhibit 4798.

2 A. Okay.

3 Q. This is an email from Bret Baird. It's dated 2010. And  
4 this, I believe, was discussed at your deposition.

5 Have you seen this before?

6 A. I have some recollection of going over it at the  
7 deposition, sir, yes.

8 Q. All right. And were you aware that on April 28, 2010 --  
9 who is Bret Baird, by the way?

10 A. I believe -- I don't know his official title, but I believe  
11 he was product manager for IVC filters.

12 Q. And if there was a communication that the Eclipse was --  
13 the sales and promotion of Eclipse filters had to start in  
14 April 2010, is that something you would have expected to  
15 receive?

16 A. Yes. I think that -- yes, sir.

17 Q. Okay. It's directed to the sales team. True?

18 A. Yes, sir, it is.

19 Q. And you were a member of the sales team back at that time  
20 in 2010; correct?

21 A. I was, sir.

22 MR. O'CONNOR: Move for the admission of Exhibit 4798.

23 THE COURT: I thought it was 8036.

24 MR. O'CONNOR: 4798.

25 MS. HELM: Can we get the exhibit so we can see the

1 exhibit number on the bottom, please?

2 MR. O'CONNOR: I'm sorry.

3 THE COURT: So I thought you said this was 8036. What  
4 is this?

5 MR. O'CONNOR: Pardon me?

6 THE COURT: You earlier referred to this as 8036.

7 This is 47 --

8 MR. O'CONNOR: I put up a new one. I'm sorry. This  
9 is 4798.

10 THE COURT: Okay. So you're moving for the admission  
11 of 4798?

12 MR. O'CONNOR: Yes.

13 MR. CONDO: No objection.

14 THE COURT: Admitted.

15 (Exhibit No. 4798 admitted into evidence.)

16 BY MR. O'CONNOR:

17 Q. Now, this is an email from Bret Baird. Do you see that,  
18 Mr. Hug?

19 A. I do, sir.

20 Q. And it's a communication to the sales team; right?

21 A. It is, sir.

22 Q. And it talks about officially stop selling the G2X in the  
23 United States.

24 Do you see that?

25 A. I do.

1 Q. And that there -- you --

2 MR. O'CONNOR: Oh, may I publish this to the jury,  
3 Your Honor?

4 THE COURT: You may.

5 BY MR. O'CONNOR:

6 Q. And let's just go back to what we talked about at the  
7 beginning.

8 According to Mr. Baird, he states to the sales team  
9 that Bard has officially stopped selling the G2X in the United  
10 States and have transitioned over to the Eclipse.

11 Correct?

12 A. Yes, sir. That's what it says.

13 Q. And he asks the question: Have your customers successfully  
14 switched over to?

15 Did I read that correctly?

16 A. Yes, sir, you did.

17 Q. And it goes on to say: If you haven't had a chance to tell  
18 all of your customers regarding the transition from the G2X to  
19 the Eclipse, now is the time to reach out and check in on them.

20 Now, did I read that correctly?

21 A. You did, sir.

22 Q. And that would be something that you would, with your sales  
23 force, carry out that directive and see that it would happen  
24 within your region; fair?

25 A. Yes. That would be fair. I would take that direction and



1 work with my team.

2 Q. All right. Now, let me show you Exhibit 4806. And this is  
3 the beginning of an email chain. And you can see at page 4 --  
4 can we go to page 4?

5 You are on this email thread from Cynthia Haas. Do  
6 you see that?

7 A. I do, sir.

8 Q. And Ms. Haas was somebody who worked at Wheaton Franciscan  
9 Healthcare; is that right?

10 A. That is accurate, sir. She worked at Wheaton Franciscan  
11 Healthcare, yes, sir.

12 Q. And she directed a request to her, and you responded to her  
13 request in the same email; is that right?

14 A. That is correct, sir.

15 Q. And if we go to page 5.

16 This is Ms. Haas's statement to you in an email, and  
17 you responded to this; correct?

18 A. I'm just trying to understand the context. I believe this  
19 is her first email. Am I looking at this right, sir?

20 Q. I believe that's correct.

21 A. Okay. That's how I see this.

22 So, yes, to answer your question, she sent me an email  
23 and then I responded to it.

24 MR. O'CONNOR: I move for the admission of 4806.

25 MR. CONDO: Hearsay objection, Your Honor.

1 THE COURT: What's your response on hearsay?

2 MR. O'CONNOR: Well, my response is is that this is an  
3 email. In the course and scope of his employment, he responds  
4 to the email. It's a request by a customer about a device.

5 THE COURT: I understand all of that. Why is it not  
6 hearsay?

7 MR. O'CONNOR: Because it's an exception to the  
8 hearsay rule.

9 THE COURT: Which one?

10 MR. O'CONNOR: I'll have to get it.

11 THE COURT: You mean as a business record?

12 MR. O'CONNOR: Yes.

13 THE COURT: You need to lay the foundation under  
14 803(6) then.

15 MR. O'CONNOR: Well, let me -- can we go to page 4?

16 BY MR. O'CONNOR:

17 Q. In response to Cynthia Haas, you responded to her; correct?

18 A. I did respond to her, sir.

19 Q. And at that time you were regional sales manager for Bard;  
20 is that right?

21 A. Just to clarify, I was district, but yes, sir. I was a  
22 district manager, yes, sir.

23 Q. District manager.

24 And your communication was done within the course and  
25 scope of your employment as the district manager for Bard;

1 correct?

2 A. Yes, sir.

3 MR. O'CONNOR: So, Your Honor, I'd move under --  
4 excuse me. Let me find it.

5 I'm taking the position, Your Honor, this is not  
6 hearsay, and I draw your attention to 801(d)(1), (2),  
7 subsection (A) and subsection (D).

8 THE COURT: Your response, Mr. Condo?

9 MR. CONDO: Your Honor, I think -- I think the  
10 totality of the exhibit violates Rule 805. Because each of the  
11 combined statements -- there has not been a showing that the  
12 combined statements conform to an exception to the hearsay  
13 rule, particularly with respect to communications not between  
14 this witness and the recipient of the document.

15 THE COURT: Well, I don't have a copy of the document  
16 so I can't tell if there's other communications between --

17 MR. O'CONNOR: Would you like to see the entire copy?

18 THE COURT: Yeah. If you want me to rule on that, I  
19 need to see the whole thing.

20 MR. O'CONNOR: Should we approach?

21 THE COURT: Sure. Hand it to Traci.

22 What communications are you referring to, Mr. Condo?

23 MR. O'CONNOR: Well, right now I'm at --

24 THE COURT: Mr. Condo.

25 MR. CONDO: If you start on the first page, Your

1 Honor, the -- and this is actually working backwards in time.  
2 The last email, but it's on the top one on the first page, then  
3 the second email on the first page.

4 THE COURT: Well, I'm not understanding that. The top  
5 one on the first page is --

6 MR. CONDO: Ms. Haas.

7 THE COURT: To?

8 MR. CONDO: Mr. Fermanich.

9 THE COURT: Right.

10 MR. CONDO: That's the first one I'm referring to.

11 THE COURT: And you're saying that's not a statement  
12 by an agent of Bard for purposes of 801(d)? Is that what  
13 you're saying?

14 MR. CONDO: I am saying she is the author.

15 THE COURT: What's your response to hearsay within  
16 hearsay?

17 MR. O'CONNOR: Well, I think that goes to notice. I  
18 think it goes to -- it's relevant to a material fact that they  
19 placed at issue, and I think it's the best evidence that we  
20 have.

21 THE COURT: Well, none of that addresses the hearsay  
22 problem. Are you saying that portions of this are not admitted  
23 for the truth of the matter asserted?

24 MR. O'CONNOR: Right.

25 THE COURT: Which portions?

1 MR. O'CONNOR: Well, her contact to Mr. Fermanich is  
2 being offered for notice, and what is key there is going to be  
3 Mr. Fermanich's response to her.

4 THE COURT: Well, so why don't you just admit  
5 Mr. Fermanich's response, which I think -- well, wait a minute.  
6 Mr. Fermanich's response or Mr. Hug's response?

7 MR. O'CONNOR: Well, Mr. Hug and then Mr. Fermanich  
8 under the same theory.

9 THE COURT: These are within the course and scope of  
10 an agent; right?

11 MR. CONDO: They are.

12 THE COURT: So those would come in under 801(d).  
13 Correct?

14 MR. CONDO: Mr. Fermanich's would, correct.

15 THE COURT: Right. So it's the Haas statements that  
16 you're --

17 MR. CONDO: Correct.

18 THE COURT: Okay. Can you just go with the admission  
19 of what Mr. Fermanich and Mr. Hug said?

20 MR. O'CONNOR: I have to see it.

21 THE COURT: Sorry, ladies and gentlemen, to take your  
22 time on this, but we need to abide by the rules of evidence.

23 MR. O'CONNOR: Felice, would you go to page 2, please.

24 BY MR. O'CONNOR:

25 Q. Mr. Hug, do you see page 2 is an email from Mr. Fermanich

1 dated April 21, 2011?

2 A. I do, sir.

3 Q. And it is an email whereby he is discussing issues that are  
4 relevant to the course and scope of his employment as a sales  
5 representative for Bard?

6 A. I would say so, sir.

7 MR. O'CONNOR: Move for the admission of at least  
8 page 2, Your Honor.

9 THE COURT: Any objection?

10 MR. CONDO: No objection, Your Honor.

11 THE COURT: All right. So the April -- can you put  
12 that back up, please?

13 The April 21st, 2011, email on page 2 is admitted, by  
14 Mr. Fermanich.

15 (Exhibit No. 4806, page 2 admitted into evidence.)

16 BY MR. O'CONNOR:

17 Q. And, Mr. Hug, let's just talk about this date. This is  
18 April 21, 2011. And this is an email from Matt Fermanich to  
19 Cynthia Haas, who as you have told us was at Wheaton Franciscan  
20 Hospital; correct?

21 MR. O'CONNOR: Oh, may I publish this document, Your  
22 Honor? I'm sorry. It's late.

23 THE COURT: Yes.

24 THE WITNESS: Yes, she was an employee of Wheaton; and  
25 it was sent by Matt, yes, sir.

1 BY MR. O'CONNOR:

2 Q. And Mr. Fermanich tells Ms. Haas, who is a customer of  
3 Bard, on April 21, 2011, that: We have a new filter called the  
4 Eclipse, which is of the same design of the G2 but has a few  
5 new features included.

6 Do you see that?

7 A. I do, sir.

8 Q. And then we can read the rest. He goes on to talk about  
9 the Eclipse and how it -- the electropolishing on the Eclipse.

10 Do you see that?

11 A. Yes. I -- yes, I see two sentences having to do with that,  
12 sir; yes, sir.

13 Q. Now, Mr. Hug, you were aware that the company had directed  
14 the sales force earlier to change out, in 2010, the G2X and  
15 replace it with the Eclipse; correct?

16 We talked about that in about April of 2010; do you  
17 recall that?

18 A. The conversation we just had; yes, sir, I do.

19 Q. And here is a Wisconsin healthcare provider who a year  
20 later is contacting Matt Fermanich, and Matt Fermanich is  
21 explaining the Eclipse and the need to replace the G2X.

22 Do you see that in this document?

23 A. I see -- yes, sir, I do.

24 Q. All right. Thank you.

25 And is it fair to say that Bard was promoting the

1 Eclipse, at least telling customers that the Eclipse had some  
2 type of improvement over the G2/G2X?

3 A. I think it's fair to say that my folks at the time and us,  
4 we were communicating that there were some differences between  
5 the Eclipse and G2X. For example, here it says the  
6 electropolished, it says here, sir.

7 Q. All right. And do you know if after this contact, this  
8 hospital, Wheaton Franciscan, received the change-out, the  
9 Eclipse, after April -- excuse me, April 21, 2011?

10 A. I'd have to look at the sales records again, but I would  
11 assume that eventually they did, sir, yes.

12 Q. And by the way, these hospitals have many different  
13 departments that you dealt with; correct?

14 A. Yes. There's an OR, which is where the surgeries happen;  
15 there's a cath lab, where they do a lot of heart procedures;  
16 and then there's an IR, which is called interventional  
17 radiology, where they do a lot of -- like, they put catheters  
18 in and PICC lines and ports and those types of things. So,  
19 yes, I dealt with all three.

20 Q. So you may receive different orders from different devices  
21 from a number of different departments within a single  
22 hospital?

23 A. Yeah. That's very fair, yes, sir.

24 Q. And that may include a special request from a doctor in a  
25 department that wants a device to be sent to him or her on a



1 specific day for a patient; correct?

2 A. Yeah. That does happen, sir, yes.

3 Q. But for the most part, in Wheaton Franciscan Hospital, you  
4 understood that Bard was promoting the IVC filters and that  
5 these hospitals were purchasing them and keeping them stocked;  
6 right?

7 A. Yes. I do believe that at Wheaton Franciscan, which had  
8 multiple hospitals and then multiple, right, parts of the  
9 hospital that would put in filters, I believe that they kept  
10 most of them stocked at all times, yes, sir.

11 I think I answered that.

12 MR. O'CONNOR: May I show Mr. Hug Exhibit 4804?

13 And if you would like, if it may be easy for Mr. --  
14 easier for Mr. Hug if I show him -- this is an email thread.  
15 And can I give him this page rather than stand here and flip  
16 through it on the computer?

17 THE COURT: Yeah. Hand it to Traci. She can do that.

18 THE WITNESS: Thank you.

19 MR. O'CONNOR: Your Honor, at this time --

20 BY MR. O'CONNOR:

21 Q. First of all, do you see that that's an email thread? That  
22 includes Matt Fermanich responding to a customer; correct?

23 A. Yes, sir.

24 Q. And within the course and scope of his employment as a  
25 sales rep, it would be typical for him to receive an email from

1 a customer who may have a question about a device; correct?

2 A. Yes, sir.

3 Q. And that's what's going on in that email; true?

4 A. That is true, sir.

5 Q. And Mr. Fermanich has responded to that email, and he  
6 responded on February 16; 2011; is that right?

7 A. He did, sir.

8 Q. And he is advising -- in February 16, 2011, he is  
9 communicating with yet another representative of Wheaton  
10 Franciscan Hospital; correct?

11 A. Yes, sir, he is.

12 Q. And he is advising her that she wants to order the Eclipse  
13 at that point in time?

14 A. It looks like that, sir, yes.

15 Q. Not the G2X?

16 A. It's not sir; it's the Eclipse, yes, sir.

17 MR. CONDO: Your Honor --

18 MR. O'CONNOR: I move for admission of --

19 THE COURT: Hold on.

20 MR. CONDO: I would object to the witness being asked  
21 questions about the content of the document until it's  
22 admitted.

23 MR. O'CONNOR: Well, I would ask to admit 4804, Your  
24 Honor.

25 THE COURT: Your response?

1 MR. CONDO: I would object to those portions that  
2 contain the hearsay of statements by Mary Christine Starr to  
3 Mr. Fermanich.

4 MR. O'CONNOR: It goes to notice again, Your Honor,  
5 and Mr. Fermanich's -- the reason for him responding to her.  
6 And it goes to the separate issue of the product  
7 identification.

8 THE COURT: Well, its relevancy doesn't solve the  
9 hearsay problem.

10 MR. O'CONNOR: Well, Your Honor, I think it goes --

11 THE COURT: I don't understand what you mean when you  
12 say it goes to notice.

13 MR. O'CONNOR: For us and our position, this is the  
14 best evidence we can provide on the product --

15 THE COURT: That doesn't overcome the hearsay  
16 objection either.

17 MR. O'CONNOR: Well, I would ask you to look at the  
18 residual rule, Rule 807(a)(2). It's being offered as evidence  
19 of a material fact.

20 THE COURT: That's not -- there are four requirements  
21 in Rule 807. It has to satisfy all four of the requirements in  
22 Rule 807.

23 MR. O'CONNOR: I'll move now for -- just for the  
24 admission of Matt Fermanich's response that we see on the  
25 second part of page 1, if that's okay, then.

1 THE COURT: Any objection?

2 MR. CONDO: No objection, Your Honor.

3 THE COURT: Okay. We will admit the second part of  
4 page 1.

5 (Exhibit No. 4804, page 1, second part admitted into  
6 evidence.)

7 MR. O'CONNOR: All right. May I publish to the jury,  
8 Your Honor?

9 THE COURT: Yes.

10 BY MR. O'CONNOR:

11 Q. And here, again, this is a month earlier, February 16,  
12 2011.

13 Do you see that, Mr. Hug?

14 A. I do, sir.

15 Q. From Matt Fermanich to Mary Christine Starr.

16 Do you see that?

17 A. I do.

18 Q. And Mary Christine Starr worked at Wheaton Franciscan  
19 Hospital; is that correct?

20 A. Yes. She worked at the Wheaton Franciscan Hospital in  
21 Franklin, sir, yes.

22 Q. And here, Matt is telling her as of February 16, 2011, not  
23 quite a year after the launch of the Eclipse, that she wants  
24 and should order the Eclipse.

25 Fair reading?

1 A. That's how I read that, sir, yes.

2 Q. Do you recall having discussions with Matt about the need  
3 to get the device changed out from the G2/G2X to the Eclipse  
4 back at that period of time?

5 A. I don't remember. It was a while ago. And I don't  
6 remember -- are you asking specifically about this account?

7 Q. About Matt --

8 A. Yeah.

9 Q. -- being delayed on getting the word out to the medical  
10 community that they should be changing the G2/G2X for the  
11 Eclipse.

12 A. I can't recall having that conversation with Matt.

13 Q. But today you've seen two examples where he was a year late  
14 in doing so. Fair?

15 A. I don't -- no. I don't think that's fair. I don't know  
16 about late. Hospitals actually at times move at their own  
17 pace. Right? They have processes. They have systems. They  
18 have structure.

19 Q. Bad question.

20 A. Okay. Sorry.

21 Q. Let me try it again.

22 You have seen emails that show that Matt was first  
23 communicating about the Eclipse almost a year after it was  
24 released, if it was released in April of 2010. Is that fair?

25 A. If it was, that would be fair, sir.

1 Q. Thank you.

2 Now, you knew Dr. David Henry; correct?

3 A. I called on Dr. Henry as his representative, sir, yes.

4 Q. I thought it appeared to me that he was somebody you knew  
5 fairly well in your world back there.

6 A. I can put it in perspective for you. I probably talked --  
7 called on him probably 20, 30 times over my years of calling on  
8 him as a rep, so yeah.

9 Q. He was an important customer of Bard's in that area?

10 A. I would say every customer is important for Bard, but --

11 Q. Good answer.

12 A. Yes.

13 Q. That's why you're good at what you do.

14 A. Sure.

15 Q. But he was somebody that you saw frequently; correct?

16 A. I would say I saw him -- sorry. I would say that I saw him  
17 frequently, sure, yes, sir.

18 Q. And he's a doctor that both you and Matt promoted products  
19 and devices to; correct?

20 A. We did have conversations and promote product, yes, sir.

21 Q. And he was a doctor, I imagine, you knew who was a doctor  
22 that listened and trusted you?

23 A. Yeah. We -- you would have to ask him that. But I believe  
24 I had a good relationship, actually, with him, if I recall  
25 correctly. And we often discussed, actually, clinician or

1 patients in different types of films and those types of things,  
2 sir.

3 Q. And if you discussed a product and a device with Dr. Henry,  
4 he would listen to you?

5 A. I think he would -- sure, he would listen to me, just like  
6 he listens to a lot of people. But yes, sir, I'm sure he would  
7 listen to me.

8 Q. He was familiar with Bard devices, including IVC filters;  
9 fair?

10 A. Yeah, I would say he was familiar with them, yes, sir.

11 Q. And he knew the various different names and brands of Bard  
12 filters; correct?

13 A. I -- you would have to ask him that. I don't know for  
14 sure. Obviously there was innovation along the way there;  
15 right? So -- but he knew Bard filters. How about that?

16 Q. And he certainly would be a doctor who you would have  
17 promoted the G2 and the G2X to; correct?

18 A. Yes. I would have communicated and talked to him about  
19 clearly the G2, the G2X, and the various innovation iterations  
20 we had, yeah.

21 Q. From your perspective, he was a doctor who knew what a G2  
22 and a G2X was; right?

23 A. Are you asking about the differences or just --

24 Q. About those filters. He knew the G2 line of filters?

25 A. He did, sir, yes.

1 Q. And do you recall giving your deposition in this matter?

2 Do you recall being asked if you would be surprised if  
3 in March of 2011 that there were still G2s and G2Xs being  
4 promoted in your region, including Milwaukee?

5 A. There are a lot of dates here. Let me take it back.

6 So March of 2011 -- why don't you just ask the  
7 question again, sir, if you could?

8 Q. Sure.

9 Do you recall testifying about you would -- it would  
10 not have surprised you if your sales reps were still promoting  
11 the G2 and G2X in March of 2011?

12 A. I can't recall that specific question in the deposition.  
13 That very well could have happened, sir.

14 Q. So you have no reason to disagree with that?

15 A. I think I would just -- if you're asking me the question  
16 now -- are you asking me the question now?

17 Q. Yeah.

18 A. I probably would say that it would not surprise me that due  
19 to that there's ORs and there's IRs and cath labs and multiple  
20 hospitals within the Wheaton Franciscan system, that there were  
21 probably some places that had G2s, because some physicians  
22 wanted G2s; there's some physicians that had G2X; you know,  
23 there's some -- and some sites that had Eclipse.

24 Q. And I think your point at deposition was if Bard wanted a  
25 product to be transitioned, that where you were working in that



1 Milwaukee area, that could take a while?

2 A. It very well could because of those administrative  
3 processes for each hospital and the different bureaucracies and  
4 committees that you have to sort of work through. So I -- it  
5 would, sir.

6 Q. Let me show you --

7 Excuse me. I've got to regroup here.

8 A. Sure.

9 Q. I had to switch my areas before I started talking to you,  
10 Mr. Hug, and I apologize. I just got a little bit out of order  
11 here.

12 MR. O'CONNOR: Let's show Exhibit 4842.

13 BY MR. O'CONNOR:

14 Q. Now, Mr. Hug, if you look at the top of this, this is an  
15 email dated March 8, 2011.

16 Do you see that?

17 A. I do.

18 Q. And that's an email from you to a number of people on your  
19 sales force; correct?

20 A. Yes, sir.

21 Q. And you're forwarding an email from Bret Baird; correct?

22 A. Yes, sir.

23 Q. And the subject of the email is Bard devices, and  
24 information that is necessary for the sales force to carry out  
25 their responsibilities while acting in the course and scope of

1 their responsibilities for Bard. Fair?

2 I'm just asking you if that's a fair summary of the  
3 email.

4 A. Yes, sir.

5 Q. I mean, it was important enough for you to forward to your  
6 sales staff; right? If you look at the top email.

7 A. Yes. It looks like we were going on backorder with the G2  
8 filter.

9 MR. O'CONNOR: I move to admit Exhibit 4842.

10 MR. CONDO: No objection.

11 THE COURT: Admitted.

12 (Exhibit No. 4842 admitted into evidence.)

13 BY MR. O'CONNOR:

14 Q. All right. Let's talk about this.

15 A. Okay.

16 Q. Here we are, and I'm just still staying in the March time  
17 period. We looked at emails in February of 2011 and we looked  
18 at emails in April of 2011. And now we're at March 2011.

19 Do you see that?

20 MR. O'CONNOR: Oh, I'd move to publish -- I'd request  
21 to publish this to the jury, Your Honor.

22 THE COURT: You may.

23 THE WITNESS: Yes, sir, I do see that.

24 BY MR. O'CONNOR:

25 Q. And the email that you were forwarding was from Bret Baird.

1 And, again, could you tell the members of the jury who  
2 Mr. Baird was?

3 A. Bret Baird is the sort of product manager for the IVC  
4 filter line.

5 Q. And he's telling you, a district manager -- well, he's  
6 advising DMs, district managers, that in the next day or so, we  
7 will be going on backorder for the femoral G2 filter as a  
8 result of the Meridian delay.

9 Did I read that correctly?

10 A. You did read that correct, sir.

11 Q. He said: As you are aware, we had been working to finish  
12 the remaining G2 product in preparation for discontinuation,  
13 but with the Meridian delay, we have turned production back on  
14 temporarily.

15 Did I read that correctly?

16 A. You did, sir.

17 Q. He said: We should be out of backorder by next week.

18 Did I read that correctly?

19 A. You did, sir.

20 Q. And he said: At this time, we do not foresee a backorder  
21 for the G2 Jug system since we have enough product to cover us.

22 A. Yes, sir.

23 Q. Did I read that correctly?

24 A. Yes, sir.

25 Q. And from your perspective as a DM, the Meridian was a new

1 device that you had been talked to, trained, and you were  
2 training your sales force about in terms of IVC filters;  
3 correct?

4 A. Yeah. I don't know about the timing of that, but prior to  
5 launch we would do training, sir.

6 Q. All right. And you understood that before March 8th, 2011,  
7 Bard had been in the development process and the testing  
8 process of the Meridian; right?

9 A. I don't remember the timeline, sir.

10 Q. But wouldn't that make sense; if they were talking about  
11 launching it, there had to be activity before that?

12 A. It would, sir. Yes, sir.

13 Q. And you recall that the features of the Meridian was that  
14 it had caudal anchors on the shoulders of the arms and caudal  
15 anchors on the feet of some of the legs of the filter; right?

16 A. I believe so, sir, yes.

17 Q. I mean, the feature was to reduce or eliminate the caudal  
18 migration that was perplexing and haunting the G2, G2X, and  
19 Eclipse. Fair?

20 A. I don't know about the haunting, but --

21 Q. Well, bad question.

22 A. I think what -- yeah.

23 Q. You knew that the G2, G2X, and even Eclipse had problems  
24 with caudal migration?

25 A. Yeah, I believe that there were complications at times with

1 filters, and I believe that the caudal anchors were probably  
2 built to address some of those complications. But you would  
3 have to ask an engineer, sir.

4 Q. I understand. But --

5 A. Yeah.

6 Q. -- engineers and people like that taught you in sales;  
7 right?

8 A. That is true. They do.

9 Q. And what you were taught in sales is that this Meridian's  
10 going to be very good because it's going to increase stability  
11 of the filter when it's in the vena cava. Fair?

12 A. I think it's fair that they would actually present it that  
13 way, that it would potentially minimize some movement, sir.

14 THE COURT: All right. We're going to break at this  
15 time, ladies and gentlemen.

16 We're going to break until Monday. Please remember  
17 Monday we're just here in the afternoon because of other  
18 reasons in the morning that have to be attended to. So if you  
19 could be here and ready to go at 1:00 o'clock, we'll get  
20 started right then.

21 You're going to have a long weekend. Please keep in  
22 mind the admonition not to discuss the case, not to do any  
23 research about it on your own.

24 Anything we need to address before we excuse the jury,  
25 counsel?

1 MR. O'CONNOR: Nothing from us.

2 MR. ROGERS: No, Your Honor.

3 THE COURT: Okay. Have a good weekend. Thank you  
4 all.

5 (Jury not present.)

6 THE COURT: Please be seated.

7 MR. O'CONNOR: Can the witness --

8 THE COURT: Yeah, you can step down. Thanks.

9 THE WITNESS: Okay. Thank you.

10 THE COURT: Counsel, so we can talk about issues  
11 before we start on Monday, let's have you here at 12:30.

12 MR. O'CONNOR: Yes.

13 MR. ROGERS: Yes, Your Honor.

14 THE COURT: And we'll address any issues.

15 Are there matters we should address before we break  
16 today?

17 MR. O'CONNOR: None that I can think of.

18 THE COURT: Well, where do you want to leave the issue  
19 we were discussing at sidebar?

20 MR. O'CONNOR: Well, I think we need time to -- it's  
21 late in the day, as everybody said, Your Honor, and I really  
22 think that we need time to look at that over the weekend so we  
23 can present to you our best argument on that issue. I don't  
24 think we have to spend a lot of the Court's time, but -- and I  
25 also think that, you know, it's late in the day and obviously

1 we're getting objections to some of these parts of these  
2 exhibits, so I would like time to look at that.

3 You know, the problem is we're only going to have this  
4 witness here once and --

5 THE COURT: I understand.

6 MR. O'CONNOR: -- I would rather get as much evidence  
7 as we can on this issue done right here, right now.

8 THE COURT: Okay. If you want to work on that over  
9 the weekend --

10 MR. O'CONNOR: That's fine.

11 MR. LOPEZ: Yeah.

12 THE COURT: Okay. We'll take that up on Monday.  
13 Anything from the defendants?

14 MR. ROGERS: No, Your Honor.

15 THE COURT: Okay. We'll see you on Monday.

16 (Proceedings concluded at 4:31 p.m.)  
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C E R T I F I C A T E

I, JENNIFER A. PANCRAZ, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 22nd day of September, 2018.

s/Jennifer A. Pancratz  
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC